Original

TENNOVA Healthcare LaFollette Medical Center (Lithotripsy)

CN1508-032

CERTIFICATE OF NEED APPLICATION

FOR

TENNOVA HEALTHCARE - LAFOLLETTE MEDICAL CENTER

Initiation of Part-Time Lithotripsy Service

Campbell County, Tennessee

August 14, 2015

Contact Person:

Jerry W. Taylor, Esq.
Burr & Forman, LLP
511 Union Street, Suite 2300
Nashville, Tennessee 37219
615-724-3247

SECTION A:

APPLICANT PROFILE

1. ***Name of Facility, Agency, or Institution***

Campbell County HMA, LLC, d/b/a Tennova Healthcare--LaFollette Medical Center
Name

923 Central Avenue — **Street or Route**
Campbell — **County**
LaFollette — **City**
TN — **State**
37762 — **Zip Code**

2. ***Contact Person Available for Responses to Questions***

Jerry W. Taylor — **Name**
Attorney — **Title**
Burr & Forman, LLP — **Company Name**
jtaylor@burr.com — **Email address**
501 Union Street, Suite 2300 — **Street or Route**
Nashville — **City**
TN — **State**
37219 — **Zip Code**
Attorney — **Association with Owner**
615-724-3247 — **Phone Number**
615-724-3347 — **Fax Number**

3. ***Owner of the Facility, Agency or Institution***

Campbell County HMA, LLC — **Name**
423-907-1200 — **Phone Number**
c/o Tennova Healthcare --LaFollette Medical Center (see above) — **Street or Route**
Campbell — **County**
LaFollette — **City**
TN — **State**
37762 — **Zip Code**

4. ***Type of Ownership of Control (Check One)***

A. Sole Proprietorship
B. Partnership
C. Limited Partnership
D. Corporation (For Profit)
E. Corporation (Not-for-Profit)
F. Government (State of TN or
G. Political Subdivision)
H. Joint Venture
I. Limited Liability Company X
Other (Specify)_____

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

Organizational documentation is attached as Attachment A, 4.

5. ***Name of Management/Operating Entity (If Applicable)*** N/A

Name

Street or Route **County**

City **State** **Zip Code**

PUT ALL ATTACHMENTS AT THE END OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

6. ***Legal Interest in the Site of the Institution (Check One)***

A. Ownership
B. Option to Purchase
C. Lease of 10 Years (Initial term) X
D. Option to Lease
E. Other (Specify) _____

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

A copy of the Lease Agreement and Assignment Agreement is attached as Attachment A, 6.

7. ***Type of Institution (Check as appropriate--more than one response may apply)***

A. Hospital (Specify) General X
B. Ambulatory Surgical Treatment Center (ASTC), Multi-Specialty
C. ASTC, Single Specialty
D. Home Health Agency
E. Hospice
F. Mental Health Hospital
G. Mental Health Residential Treatment Facility
H. Mental Retardation Institutional Habilitation Facility (ICF/MR)
I. Nursing Home
J. Outpatient Diagnostic Center
K. Recuperation Center
L. Rehabilitation Facility
M. Residential Hospice
N. Non-Residential Methadone Facility
Birthing Center
O. Other Outpatient Facility
P. (Specify)_____
Other (Specify) _____
Q.

8. Purpose of Review *(Check) as appropriate--more than one response may apply)*

A.	New Institution		
B.	Replacement/Existing Facility		
C.	Modification/Existing Facility		
D.	Initiation of Health Care Service as defined in TCA § 68-11-1607(4) (Specify) Lithotripsy	X	
E.	Discontinuance of OB Services		
F.	Acquisition of Equipment		
G.	Change in Bed Complement [*Please note the type of change by underlining the appropriate response: Increase, Decrease, Designation, Distribution, Conversion, Relocation]*		
H.	Change of Location		____
I.	Other (Specify)_____		____

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9. **Bed Complement Data**

Please indicate current and proposed distribution and certification of facility beds.

		Current Beds Licensed	*CON	*Staffed* Beds	*Beds* Proposed	*TOTAL Beds at* Completion
A.	Medical/Surgical	50		50		50
B.	Surgical (included in above)					
C.	Long-Term Care Hospital					
D.	Obstetrical					
E.	ICU/CCU	6		6		6
F.	Neonatal					
G.	Pediatric					
H.	Adult Psychiatric					
I.	Geriatric Psychiatric	10		10		10
J.	Child/Adolescent Psychiatric					
K.	Rehabilitation					
L.	Nursing Facility (non-Medicaid Certified)					
M.	Nursing Facility Level 1 (Medicaid only)					
N.	Nursing Facility Level 2 (Medicare only)					
O.	Nursing Facility Level 2 (dually certified Medicaid/Medicare)					
P.	ICF/MR					
Q.	Adult Chemical Dependency					
R.	Child and Adolescent Chemical Dependency					
S.	Swing Beds					
T.	Mental Health Residential Treatment					
U.	Residential Hospice					
	TOTAL	**66**		**66**		**66**

10. **Medicare Provider Number:** 440033
Certification Type: Hospital

11. **Medicaid Provider Number:** 0440033
Certification Type: Hospital

12. **If this is a new facility, will certification be sought for Medicare and/or Medicaid?**

Tennova Healthcare Lafollette Medical Center is certified for both programs.

13. **Identify all TennCare Managed Care Organizations/Behavioral Health Organizations (MCOs/BHOs) operating in the proposed service area.**

AMERIGROUP

BlueCare

UnitedHealthcare Community Plan

TennCare Select

Will this project involve the treatment of TennCare participants?

Yes

If the response to this item is yes, please identify all MCOs/BHOs with which the applicant has contracted or plans to contract.

The applicant is contracted with of the TennCare MCOs operating in the area.

Discuss any out-of-network relationships in place with MCOs/BHOs in the area.

N/A

NOTE: ***Section B*** **is intended to give the applicant an opportunity to describe the project and to discuss the need that the applicant sees for the project.** ***Section C*** **addresses how the project relates to the Certificate of Need criteria of Need, Economic Feasibility, and the Contribution to the Orderly Development of Health Care. Discussions on how the application relates to the criteria should not take place in this section unless otherwise specified.**

SECTION B: PROJECT DESCRIPTION

Please answer all questions on 8 1/2" x 11" white paper, clearly typed and spaced, identified correctly and in the correct sequence. In answering, please type the question and the response. All exhibits and tables must be attached to the end of the application in correct sequence identifying the questions(s) to which they refer. If a particular question does not apply to your project, indicate "Not Applicable (NA)" after that question.

I. Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility and staffing.

Project Description

The applicant, Campbell County HMA, LLC, d/b/a Tennova Healthcare -- LaFollette Medical Center (hereafter "TH-LMC") proposes to initiate extracorporeal shockwave lithotripsy ("ESWL" or "lithotripsy") services up to three days per week though the use of a leased mobile lithotripsy unit. The applicant seeks authorization for up to three days per week. The services will be provided in existing space on the TH-LMC campus. There is no construction or renovation involved in this project.

Services & Equipment

Services to be provided are lithotripsy treatments. The equipment is a HealthTronics LithoDiamond Multifunctional Lithotripsy System.

Ownership Structure

The owner of the hospital is Campbell County, HMA, LLC. It is affiliated through several subsidiaries with Community Health Systems, Inc. An organizational chart of the ownership is attached as Attachment B, I.

Service Area

The proposed service area consists of Campbell, Claiborne and Scott counties. Residents of these three counties accounted for 89% of admissions at TH-LMC in 2013.

Need

There is no lithotripsy unit located in the 3 county service area. The closest units are located approximately 45 minutes' to one hour drive time in Knox County and Anderson County.

Until recently, TH-LMC did not have an urologist on its medical staff. In August, 2015 Dr. Sean DeLair, a board certified Urologist, relocated his practice from Kentucky to LaFollette. Dr.

DeLair is trained and has significant experience in delivering lithotripsy treatments. He knows from experience there is a need for lithotripsy services in rural communities so patients do not have to travel to urban areas to receive needed treatment.

A significant number of patients present at the TH-LMC emergency department who are discharged with a diagnosis of "Possible Urology." Between 2013-2015 the number of such E.D. visits averaged 358 patients per year. Not all of these are kidney stone cases or candidates for lithotripsy, but some undoubtedly are, and this further supports the need for the lithotripsy service at TH-LMC.

Prior to Dr. DeLair's arrival at TH-LMC, these patients could not be treated at the hospital. Now that Dr. DeLair in on the medical staff, lithotripsy services can be offered at TH-LMC, providing local access to needed care for service area residents.

Existing Resources

There is no lithotripsy unit located in the 3 county service area. The closest units are located approximately 45 minutes' to one hour drive time in Knox County and Anderson County.

Project Cost & Funding

The project cost is $437,203, exclusive of the filing fee. The project will be funded through operating revenues, or, if necessary, the cash reserves of CHS / Community Health Systems, Inc.

Financial Feasibility

The project is financially feasible. It will be profitable in its first year of operation and thereafter. There are no capital expenditures required.

Staffing

Staffing will include a RN, a surgical tech, a CRNA, and a radiological technologist, all on a part-time basis. The radiological technologist is supplied by the mobile vendor. The applicant will not have to increase its staff for this project.

II. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal.

A. Describe the construction, modification and/or renovation of the facility (exclusive of major medical equipment covered by T.C.A. § 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc. Applicants with hospital projects (construction cost in excess of $5 million) and other facility projects (construction cost in excess of $2 million) should complete the Square Footage and Cost per Square Footage Chart. Utilizing the attached Chart, applicants with hospital projects should complete Parts A.-E. by identifying as applicable nursing units, ancillary areas, and support areas affected by this project. Provide the location of the unit/service within the existing facility along with current square footage, where, if any, the unit/service will relocate temporarily during construction and renovation, and then the location of the unit/service with proposed square footage. The total cost per square foot should provide a breakout between new

construction and renovation cost per square foot. Other facility projects need only complete Parts B.-E. Please also discuss and justify the cost per square foot for this project.

N/A. No construction or renovation is involved in this project.

If the project involves none of the above, describe the development of the proposal.

The mobile lithotripsy unit is easily moved on attached wheels from place to place as needed. The unit is lightweight and compact. Most days it will be located in the cystology procedure room located in the surgery department. If for some reason the cystology room is not available, the lithotripsy can be used in either of the two operating rooms in the department.

B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and/or redistributed by this application. Describe the reasons for change in bed allocations and describe the impact the bed change will have on the existing services.

N/A.

SQUARE FOOTAGE AND COST PER SQUARE FOOTAGE CHART N/A

A. Unit / Department	Existing Location	Existing SF	Temporary Location	Proposed Final Location	Proposed Final Square Footage			Proposed Final Cost/ SF		
					Renovated	New	Total	Renovated	New	Total
B. Unit/Depart. GSF Sub-Total										
C. Mechanical/ Electrical GSF										
D. Circulation /Structure GSF										
E. Total GSF										

C. **As the applicant, describe your need to provide the following health care services (if applicable to this application):**

Extracorporeal Lithotripsy:

There is no lithotripsy unit located in the 3 county service area. The closest units are located approximately 45 minutes' to one hour drive time in Knox County and Anderson County.

Until recently, TH-LMC did not have an urologist on its medical staff. In August, 2015 Dr. Sean DeLair, a board certified Urologist, relocated his practice from Kentucky to LaFollette. Dr. DeLair is trained and has signinficant experience in delivering lithotripsy treatments. He knows from experience there is a need for lithotripsy servies in rural communites so pateints do not have to travel to urban areas to receive needed treatment.

A significant number of patients present at the TH-LMC emergency department who are discharged with a diagnosis of "Possible Urology." Between 2013-2015 the number of such E.D. visits averaged 358 patients per year. Not all of these are kidney stone cases or candidates for lithotripsy, but some undoubtedly are, and this further supports the need for the lithotripsy service at TH-LMC.

Prior to Dr. DeLair's arrival at TH-LMC, these patients could not be treated at the hospital. Now that Dr. DeLair in on the medical staff, lithotripsy services can be offered at TH-LMC, providing local access to needed care for service area residents.

D. Describe the need to change location or replace an existing facility.

N/A

E. Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of $2 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:

1. For fixed-site major medical equipment (not replacing existing equipment):

N/A.

a. Describe the new equipment, including:

1. Total cost (As defined by Agency Rule).

2. Expected useful life;

3. List of clinical applications to be provided; and

4. **Documentation of FDA approval.**

b. Provide current and proposed schedules of operations.

2. For mobile major medical equipment:

a. List all sites that will be served;

During the applicant's leased time, the unit will be located on the hospital campus.

b. Provide current and/or proposed schedule of operations;

The exact days the unit will be used have not been determined. Initially, the applicant plans on operating the service one day per week, until volume grows to a level justifying additional days. On the days it is on site, it will operate between the hours necessary to provide all scheduled treatments.

c. Provide the lease or contract cost.

The total of the lease payments in Year 1 (initial term of the lease) is $396,000.

d. Provide the fair market value of the equipment; and

The estimated FMV or the lithotripsy unit is $120,000 (estimated purchase price from vendor, $200,000, x 60% representing 3 days part-time use).

A letter from HealthTronics stating the estimated value of the equipment is attached as Attachment B, II, 2.

e. List the owner for the equipment.

Kentucky 1 Lithotripsy, a subsidiary of HealthTronics, Inc.

3. Indicate applicant's legal interest in equipment (*i.e.*, purchase, lease, etc.) In the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.

The equipment will be leased on a part time basis from Kentucky 1 Lithotripsy pursuant to a Mobile Lithotripsy Services Agreement. Under the Agreement, the owner provides the lithotripsy unit and one radiologic technologist. The hospital provides space for the unit, a supervising urologist, a CRNA, and any needed supplies and medications. The payment from the hospital to Kentucky 1 is $2,400 per treatment. The initial term of the agreement is one year.

A copy of the Mobile Lithotripsy Services Agreement is attached as Attachment B, II, 3.

III. (A) Attach a copy of the plot plan of the site on an 8 1/2" x 11" sheet of white paper which must include:

1. **Size of site (*in acres*);**
2. **Location of structure on the site; and**
3. **Location of the proposed construction.**
4. **Names of streets, roads or highway that cross or border the site.**

Please note that the drawings do not need to be drawn to scale. Plot plans are required for all projects.

Two plot plans are attached: (1) a Title Survey map which is not ideally legible but is all that is available, and (2) an aerial shot from Google Earth. These are attached as Attachment B, III.

(B)

1. **Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients.**

There is no public transportation service in LaFollette. The hospital is located on Central Avenue, which is a four lane highway and a major thoroughfare in the area. The hospital is easily accessible for patients and the public.

IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc. on an 8 1/2" x 11" sheet of white paper.

NOTE: *DO NOT SUBMIT BLUEPRINTS*. Simple line drawings should be submitted and need not be drawn to scale.

A floor plan drawing of the area of the hospital where the lithotripsy unit will be located is attached as Attachment B, IV.

V. For a Home Health Agency or Hospice, identify:

N/A.

1. **Existing service area by County;**
2. **Proposed service area by County;**
3. **A parent or primary service provider;**
4. **Existing branches; and**
5. **Proposed branches.**

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with Tennessee Code Annotated § 68-11-1609(b), "no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of health care." The three (3) criteria are further defined in Agency Rule 0720-4-.01. Further standards for guidance are provided in the state health plan (Guidelines for Growth), developed pursuant to Tennessee Code Annotated §68-11-1625.

The following questions are listed according to the three (3) criteria: (I) Need, (II) Economic Feasibility, and (III) Contribution to the Orderly Development of Health Care. Please respond to each question and provide underlying assumptions, data sources, and methodologies when appropriate. *Please type each question and its response on an 8 1/2" x 11" white paper*. All exhibits and tables must be attached to the end of the application in correct sequence identifying the question(s) to which they refer. If a question does not apply to your project, indicate "Not Applicable (NA)."

QUESTIONS

I. NEED

1. Describe the relationship of this proposal toward the implementation of the State Health Plan and Tennessee's Health: Guidelines for Growth.

Five Principles for Achieving Better Health from the Tennessee State Health Plan:

1. Healthy Lives

The purpose of the State Health Plan is to improve the health of Tennesseans.

Every person's health is the result of the interaction of individual behaviors, society, the environment, economic factors, and our genetic endowment. The State Health Plan serves to facilitate the collaboration of organizations and their ideas to help address health at these many levels.

This appears to be a policy statement to which no response is necessary.

2. Access to Care

Every citizen should have reasonable access to health care.

Many elements impact one's access to health care, including existing health status, employment, income, geography, and culture. The State Health Plan can provide standards for reasonable access, offer policy direction to improve access, and serve a coordinating role to expand health care access.

The proposed lithotripsy service would be the only such service in the 3 county service area. It will improve access to health care for the service area population.

3. Economic Efficiencies

The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies and the continued development of the state's health care system. The State Health Plan should work to identify opportunities to improve the efficiency of the state's health care system and to encourage innovation and competition.

This project involves no capital expense. It will be funded through operating revenues of the lithotripsy service.

4. Quality of Care

Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers. Health care providers are held to certain professional standards by the state's licensure system. Many health care stakeholders are working to improve their quality of care through adoption of best practices and data-driven evaluation.

TH-LMC is accredited by the Joint Commission and is in good stating with both the TJC and the Tennessee Departmental Health. Lithotripsy is a very safe, non-invasive treatment.

5. Health Care Workforce

The state should support the development, recruitment, and retention of a sufficient and quality health care workforce. The state should consider developing a comprehensive approach to ensure the existence of a sufficient, qualified health care workforce, taking into account issues regarding the number of providers at all levels and in all specialty and focus areas, the number of professionals in teaching positions, the capacity of medical, nursing, allied health and other educational institutions, state and federal laws and regulations impacting capacity programs, and funding.

This project does not require any additional hospital staffing, and should have no impact on the local workforce.

a. **Please provide a response to each criterion and standard in Certificate of Need Categories that are applicable to the proposed project. Do not provide responses to General Criteria and Standards (pages 6-9) here.**

EXTRACORPOREAL SHOCKWAVE LITHOTRIPSY

1. Determination of Need: The need for ESWL services is determined by applying the following formula:

N = (U X P) + 0

N =number of ESWL services procedures needed in a Service Area;

U = latest available Tennessee use rate (number of procedures performed per 1,000 population in the state as determined by the Tennessee Department of Health);

P = projection of population (in thousands) in the service area as determined by the Tennessee Department of Health tor Tennessee counties and the United States Census Bureau for non-Tennessee counties; and

0 = the number of out-of-state resident procedures performed within the applicant's Service Area in the same time frame used to determine U based upon publically reported data. The applicant should document the methodology used to count volume in out-of-state resident procedures and, if different from the definition of "procedure" described in these standards and criteria, should distinguish out-of-state procedures from in-state cases.

The need shall be based upon the Service Area's current year's population projected three years forward.

These calculations have been performed by the Department of Health for all counties in Tennessee. The results are attached as Attachment C, I, Need, 1 (1).

For the 3 county service area the calculations reflect a need for 128 treatments in 2018.

2. Minimum Volume Standard: Applicants proposing to acquire and operate an ESWL services unit must project a minimum utilization of at least 250 procedures per year by the third year of operation, based on full-time use of an ESWL unit. The applicant must also document and provide data supporting the methodology used to project the patient utilization. An application to provide ESWL services on a part-time basis shall convert its projected use to that of a full-time equivalent ESWL unit.

TH-LMC seeks authorization to operate the lithotripsy service for up to 3 days per week. The pro-rated minimum volume is 150 treatments (3/5 of 250). The applicant is projecting 165 lithotripsy treatments in Year 1.

3. Current Service Area Utilization: The applicant should document that all existing providers of ESWL services within the proposed Service Area each performed at least 300 ESWL procedures per year during the most recent 12 month period for which data are available. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit. To characterize existing providers located within Tennessee, the applicant should use data provided by the Health Services and Development Agency. To characterize providers located outside of Tennessee, the applicant should use publicly available data, if available, and describe in its application the methodology these providers use to count volume.

N/A. There are no existing providers of lithotripsy service in the service area.

In addition, the applicant should provide the HSDA with a report of patient destination for ESWL services based on the most recent 12 months of publicly reported data. This report should list all facilities that provided ESWL services to residents of the proposed Service Area and the number of ESWL procedures performed on residents of the Service Area for each facility. The Tennessee Department of Health will assist applicants in generating this report utilizing the HDDS.

The Department of Health has prepared such a s report, and it is attached as Attachment C, I, Need, 1 (2). This report shows that 148 residents of the eservice area received lithotripsy services in 2013. This is 20 more treatments than the calculated "need" for 2018.

4. Adverse Impact on Existing Providers: An application for ESWL services should not be approved if the new program will cause the annual caseload of existing ESWL programs within the Service Area to drop below an average of 300 procedures. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit. The patient origin study conducted for Standard 2, an analysis of patient origin data collected for Standard 3, and the referral data documented for Standard 3 should be used to determine whether such an adverse impact on existing providers is likely to occur.

N/A. There are no existing providers of lithotripsy service in the service area.

5. Adequate Staffing and Services: The applicant should document a plan for recruiting and maintaining a sufficient number of qualified professional and technical staff to provide the ESWL services and must document the following:

a. The existence of an active radiology service and an established referral urological practice;

A board certified urologist, Dr. Sean DeLair, has recently joined the TH-LMC medical staff after relocating his practice from Somerset, Kentucky. A letter from Dr. DeLair is attached as Attachment C, I, Need, 1 (3).

Also included in the referenced attachment is a letter from Dr. Jan Robbins, Chief of the Medical Staff and Medical Director of the E.D. Dr. Robbins attests to the need for a local lithotripsy service, and states that approximately 30 patients per month are diagnosed with kidney stones in the TH-LMC emergency department. Letters from other physicians who work in the E.D are also included.

Also included in the referenced attachment are letters from numerous physicians in the area, including internists and family practitioners. These physicians are typically referral sources for patients needing lithotripsy. All attest to the need for a local lithotripsy service.

b. The availability within 90 minutes' drive time of acute inpatient services for patients who experience complications; and

University of Tennessee Medical Center in Knox County is 48 minutes' drive time from TH-LMC.

Oak Ridge Medical Center in Anderson County is 49 minutes' drive time from TH-LMC.

Source: Google Maps

c. The fact that all individuals using the equipment meet the training and credentialing requirements of the American College of Surgeons' Advisory Council for Urology.

Dr. DeLair, who is currently the only urologist who will be the attending physician for the lithotripsy program, is board certified in Urology.

The applicant should also document an ongoing educational plan for all staff included in the ESWL services program.

The radiologic technologist trained in ESWL is provided by the equipment vendor. Under the Mobile Lithotripsy Services Agreement, the vendor is obligated to assure the technologist is properly trained and certified.

6. ESWL Equipment: Only applications that provide for the provision of ESWL services using equipment that has been approved by the United States Food and Drug Administration for clinical use shall be approvable.

A copy of the FDA approval documentation is attached as Attachment C, I, Need, 1 (4).

7. Quality Control and Monitoring: The applicant should identify and document its intention to participate in a data reporting, quality improvement, outcome monitoring, and peer review system that benchmarks outcomes based on national norms. The system should provide for peer review among professionals practicing in facilities and programs other than the applicant.

The Mobile Lithotripsy Services Agreement provides for a cooperative Quality Assurance program between the mobile vendor and the hospital. Section 4 provides the mobile vendor has the following relevant responsibilities:

> "e. Creating and maintaining a quality assurance program for monitoring and improving the efficacy of the operation of the ESL and the ESL Services provided by Provider on Hospital premises, and complying with all applicable standards of The Joint Commission (TJC) and Medicare standards, including the applicable Medicare conditions of participation for hospital contracted services currently specified at 42 CFR 482.12(e). Provider shall cooperate with Hospital's quality assurance committee in its periodic review, on a random sample basis, of services provided to Hospital patients by Provider pursuant to the terms of this Agreement. Quality assurance reports may be requested by mailing the request to the address as indicated below. Quality assurance reports will include quality assurance activities conducted;
>
> * * *
>
> g. At Hospital's request, participate in Hospital's utilization review program and any other Hospital program or committee with respect to the ESL Services that would be required if the ESL services were furnished directly by the Hospital. Furthermore, Provider shall meet with Hospital management as appropriate and necessary on a periodic basis to discuss pertinent issues relating to the arrangement and/or ESL services;"

A sample QA Report, referenced in sub-section (e) above is attached as Attachment C, I, Need, 1 (5).

8. Data Requirements: Applicants should agree to provide the Department of Health and/or the HSDA with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

The applicant so agrees.

9. Transfer and/or Affiliation Agreements: If an applicant is not a designated Level I trauma center, an applicant must document an acceptable plan for the development of transfer and/or affiliation agreements with hospitals in the service area (this criterion does not preclude the development of transfer agreements with facilities outside the applicant's Service Area).

TH-LMC has a transfer agreement with University of Tennessee Medical Center, a Level I Trauma Center. A copy is attached as Attachment C, I, Need, 1, (6).

10. Access: In addition to the factors set forth in HSDA Rule 0720-11-.01 (1) (listing the factors concerning need on which an application may be evaluated), the HSDA may choose to give special consideration to an applicant:

a. That is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

All 3 counties in the service area are designated as Medically Underserved Areas by the HRSA. Documentation is attached as Attachment C, I, Need, 1, (7).

b. That documents that the service area population experiences a prevalence and/or incidence of urinary stones or other clinical conditions applicable to extra-corporeal shock wave lithotripsy services that is substantially higher than the State of Tennessee average; or

All 3 counties in the service area have a higher lithotripsy use rate than that of the state as a whole:

County	County Use Rate	Statewide Use Rate
Campbell	.0019445	.0012927
Claiborne	.0023640	.0012927
Scott	.0015612	.0012927

This in part explains the fact that in 2013 more service area residents received lithotripsy treatments (148) than the calculated "need" for 2018 (128), the latter of which is based on the statewide use rate.

c. That is a "safety net hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program.

TH-LMC does receive Essential Access Program payments.

[End of responses to State Health Plan]

b. **Applications that include a Change of Site for a health care institution, provide a response to General Criterion and Standards (4)(a-c)**

N/A.

2. **Describe the relationship of this project to the applicant facility's long-range development plans, if any.**

The proposed lithotripsy service is not related to any other long range plans of TH-LMC.

3. **Identify the proposed service area and justify the reasonableness of that proposed area. Submit a county level map including the State of Tennessee clearly marked to reflect the service area. Please submit the map on 8 1/2" x 11"**

The proposed service area consists of Campbell, Claiborne and Scott counties. Residents of these three counties accounted for 89% of admissions at TH-LMC in 2013.

A map of the service area is attached as Attachment C, I, Need, 3.

4. **A. Describe the demographics of the population to be served by this proposal.**

B. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

A Population and Demographics Table is attached as Attachment C, I, Need, 4.

5. **Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc.**

N/A. There are no existing providers of lithotripsy service in the service area.

6. **Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization for each of the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology**

must include detailed calculations or documentation from referral sources, and identification of all assumptions.

This is a proposed new service, so there is no applicable historical utilization data.

It should be noted, however, that a high number of patients present at the TH-LMC emergency department who are discharged with a diagnosis of "Possible Urology." Since until recently TH-LMC did not have an urologist on staff, these patients could not be treated.

Year:	"Possible Urology" Diagnosed Cases:
2013	410
2014	347
2015 (Annualized 7-31)	317

Of course not all of these are kidney stone cases or candidates for lithotripsy, but some portion are and it further supports the need for the lithotripsy service at TH-LMC.

Projected Utilization:

Year 1: 165 treatments

Year 2: 180 treatments

These are reasonable projections based on the following considerations and assumptions:

1. According to outmigration data provided by the Department of Health, 148 service area residents received lithotripsy treatments in 2013.

2. An average of 358 patients per year presented at the TH-LMC emergency department and were discharged with a "Possible Urology" diagnosis between 2013-2015. While not all of these are kidney stone cases or candidates for lithotripsy some are, and this indicates the need for treatments may be higher than the 148 treatments received in 2013.

3. Letters from local physicians, including internists and family medicine physicians, who are referral sources for lithotripsy patients, indicate a need for a local lithotripsy service. Although the numbers of such potential referrals was not quantified, this physician support confirms the need for the lithotripsy service at TH-LMC.

4. All service area counties have a higher lithotripsy use rate than does the state as a whole.

5. Although the "need" for 2018 lithotripsy based on the statewide use rate is 128 treatments, the reliability of this statistic is undermined by the fact that 148 patients from the service area actually received such treatment in 2013.

6. The absence of a locally available lithotripsy service may cause the number of service area residents who receive the service to be lower than it would be if a local service was available. This would be patients who need the service but who are unable or unwilling to leave the service area to receive it.

II. ECONOMIC FEASIBILITY

1. **Provide the cost of the project by completing the Project Costs Chart on the following page. Justify the cost of the project.**

    - **All projects should have a project cost of at least $3,000 on Line F. (Minimum CON Filing Fee). CON filing fee should be calculated from Line D. (See Application Instructions for Filing Fee)**
    - **The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or "per click" arrangements. The methodology used to determine the total lease cost for a "per click" arrangement must include, at a minimum, the projected procedures, the "per click" rate and the term of the lease.**
    - **The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.**

For projects that include new construction, modification, and/or renovation; documentation must be provided from a contractor and/or architect that support the estimated construction costs.

A completed Project Cost Chart is attached on the following page.

PROJECT COSTS CHART

A.	Construction and equipment acquired by purchase:		
	1. Architectural and Engineering Fees		
	2. Legal, Administrative, Consultant Fees		$ 30,000
	3. Acquisition of Site		
	4. Preparation of Site		
	5. Construction Costs		
	6. Contingency Fund		
	7. Fixed Equipment (Not included in Construction Contract)		
	8. Moveable Equipment (List all equipment over $50,000.00)		
	9. Other (Specify)		
B.	Acquisition by gift donation, or lease:		
	1. Facility (Inclusive of building and land)		
	2. Building Only		
	3. Land Only		
	4. Equipment (Specify)	Lithotripsy Unit ($2,400/procedure)	$ 396,000.00
	5. Other (Specify)	Supplies and Medications	$ 11,203.00
C.	Financing Costs and Fees:		
	1. Interim Financing		
	2. Underwriting Costs		
	3. Reserve for One Year's Debt Service		
	4. Other (Specify)		
D.	Estimated Project Cost (A+B+C)		$ 437,203.00
E.	CON Filing Fee		$ 3,000.00
F.	Total Estimated Project Cost (D & E)		$ 440,203.00
		TOTAL	$ 440,203.00

2. **Identify the funding sources for this project.**

   a. **Please check the applicable item(s) below and briefly summarize how the project will be financed.** ***(Documentation for the type of funding MUST be inserted at the end of the application, in the correct alpha/numeric order and identified as Attachment C, Economic Feasibility-2.)***

__ **A. Commercial loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;**

__ **B. Tax-exempt bonds--Copy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;**

__ **C. General obligation bonds—Copy of resolution from issuing authority or minutes from the appropriate meeting.**

__ **D. Grants--Notification of intent form for grant application or notice of grant award; or**

X **E. Cash Reserves--Appropriate documentation from Chief Financial Officer.**

No out-of pocket capital outlay is required. This project will almost certainly be funded through operating revenues of the lithotripsy service. However, if and to the extent a capital outlay is required, a funding letter is attached as Attachment C, II, Economic Feasibility, 2.

__ **F. Other—Identify and document funding from all other sources.**

3. **Discuss and document the reasonableness of the proposed project costs. If applicable, compare the cost per square foot of construction to similar projects recently approved by the Health Services and Development Agency.**

4. **Complete Historical and Projected Data Charts on the following two pages--*Do not modify the Charts provided or submit Chart substitutions!* Historical Data Chart represents revenue and expense information for the last *three (3)* years for which complete data is available for the institution. Projected Data Chart requests information for the two (2) years following the completion of this proposal. Projected Data Chart should reflect revenue and expense projections for the *Proposal Only* (*i.e.*, if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility).**

Attached on the following pages are:

1. A Historical data Chart for the entire hospital

2. A projected Data Chart for the entire hospital.

3. A Projected Data Chart for the Lithotripsy service.

HISTORICAL DATA CHART

Give information for the last three (3) years for which complete data are available for the facility or agency.

		2012	2013	2014
A.	Utilization/Occupancy Data: Admissions	2359	2586	2416
B.	Revenue from Services to Patients			
	1. Inpatient Services	$50,801,155	$64,614,690	$ 68,585,717
	2. Outpatient Services * ER services included in Outpatient	$181,833,261	$167,394,260	$ 169,161,849
	3. Emergency Services			
	4. Other Operating Revenue	$175,961	$140,165	$ 148,430
	Specify: rental income, etc.			
	Gross Operating Revenue	$232,810,377	$232,149,115	$ 237,895,996
C.	Deductions from Operating Revenue			
	1. Contract Deductions	$153,746,090	$161,451,618	$ 168,614,728
	2. Provision for Charity Care	$8,316,056	$8,820,398	$ 8,729,992
	3. Provision for Bad Debt	$6,449,325	$5,215,629	$ 6,710,067
	Total Deductions	$168,511,471	$175,487,645	$ 184,054,787
	NET OPERATING REVENUE	$64,298,906	$56,661,470	$ 53,841,209
D.	Operating Expenses			
	1. Salaries and Wages	$14,713,218	$14,263,599	$ 14,021,991
	2. Physicians' Salaries and Wages			
	3. Supplies	$15,214,172	$12,600,913	$ 13,099,986
	4. Taxes	$588,379	$553,777	$ 551,740
	5. Depreciation	$4,020,203	$4,401,153	$ 4,085,725
	6. Rent	$1,041,434	$1,000,469	$ 650,482
	7. Interest, other than Capital			
	8. Management Fees:			
	a. Fees to Affiliates	$10,632,434	$3,380,664	$ 1,401,537
	b. Fees to Non-Alffiliates			
	9. Other Expenses	$12,480,266	$13,038,487	$ 12,515,816
	Specify: benefits, profees, outside svs, maint, etc.			
	Total Operating Expenses	$58,690,106	$49,239,062	$ 46,327,277
E.	Other Revenue (Expenses)--Net			
	Specify:			
	NET OPERATING INCOME (LOSS)	$5,608,800	$7,422,408	$ 7,513,932
F.	Capital Expenditures			
	1. Retirement of Principal			
	2. Interest			
	Total Capital Expenditures	$0	$0	$ -
	NET OPERATING INCOME (LOSS)	$5,608,800	$7,422,408	$ 7,513,932
	LESS CAPITAL EXPENDITURES	$0	$0	$ -
	NOI LESS CAPITAL EXPENDITURES	$5,608,800	$7,422,408	$ 7,513,932

historical

Other Expenses

	2012	2013	2014
benefits	3,825,998	3,865,505	4,244,916
prof. fees	546,020	210,526	201,380
outside services	3,172,182	4,073,050	4,767,219
repairs & maint	942,258	921,197	1,083,417
utilities	640,100	497,936	675,950
general insurance	845,567	604,917	740,404
other taxes	1,862,919	1,848,149	1,918,012
property tax	254,771	227,434	270,820
sales tax	333,608	326,344	191,357
other	56,844	463,429	31,549
Hitech Incentive			-1609208
	12,480,266	13,038,487	12,515,815

Other Revenue

	2012	2013	2014
OTHER REVENUE	15,440	15,654	16,577
CAFETERIA SALES	332		
GIFT SHOP SALES	14,837	3562.18	3,772
VENDING SALES	6,463	12576.15	13,318
COT RENTAL			
OTHER RENTAL	111,649	99382.95	105,243
MEDICAL TRANS.	738	620.05	657
INTEREST INCOME	1,663	-2143.1	-2,269
MISCELLANEOUS INC(	24,836	10512.89	11,133
SUPPLIES SOLD	4		
	175,961	140,165	148,430

PROJECTED DATA CHART (Whole Hospital)

Give information for the two (2) years following completion of this proposal. The fiscal year begins in _____.

		Year 1	Year 2
A.	Utilization/Occupancy Data (Admissions).	2,464	2,514
B.	Revenue from Services to Patients		
	1. Inpatient Services	$ 69,957,431	$ 71,356,580
	2. Outpatient Services	$ 174,085,793	$ 179,308,367
	3. Emergency Services	$ -	$ -
	4. Other Operating Revenue (Specify) _____	$ 148,430	$ 151,399
	Gross Operating Revenue	**$ 244,191,655**	**$ 250,816,346**
C.	Deductions from Operating Revenue		
	1. Contractual Adjustments	$ 173,253,880	$ 177,957,062
	2. Provisions for Charity Care	$ 8,959,603	$ 9,202,822
	3. Provisions for Bad Debt	$ 6,682,202	$ 6,863,605
	Total Deductions	**$ 188,895,684**	**$ 194,023,490**
NET OPERATING REVENUE		$ 55,295,971	$ 56,792,856
D.	Operating Expenses		
	1. Salaries and Wages	$ 14,305,916	$ 14,595,837
	2. Physicians' Salaries and Wages		
	3. Supplies	$ 13,236,121	$ 13,506,132
	4. Taxes	$ 551,740	$ 551,740
	5. Depreciation	$ 4,085,725	$ 4,085,725
	6. Rent	$ 650,482	$ 650,482
	7. Interest, other than Capital		
	8. Management Fees:		
	a. Fees to Affiliates	$ 1,401,537	$ 1,401,537
	b. Fees to Non-Affiliates		
	9. Other Expenses	$ 12,911,816	$ 12,923,696
	Specify: _____		
	Total Operating Expenses	$ 47,143,337	$ 47,715,149
E.	Other Revenue (Expenses)--Net		
	Specify: _____		
NET OPERATING INCOME (LOSS)		$ 8,152,633	$ 9,077,707
F.	Capital Expenditures		
	1. Retirement of Principal		
	2. Interest		
	Total Capital Expenditures	$ -	$ -
NET OPERATING INCOME (LOSS)		$ 8,152,633	$ 9,077,707
LESS CAPITAL EXPENDITURES		$ -	$ -
NOI LESS CAPITAL EXPENDITURES		$ 8,152,633	$ 9,077,707

projected

Other Expenses

	year 1	year 2
benefits	4,244,916	4,244,916
prof. fees	201,380	201,380
outside services	5,163,219	5,163,219
repairs & maint	1,083,417	1,083,417
utilities	675,950	675,950
general insurance	740,404	740,404
other taxes	1,918,012	1,918,012
property tax	270,820	270,820
sales tax	191,357	191,357
other	31,549	31,549
Hitech Incentive	-1,609,208	-1,609,208
	12,911,815	12,923,696

Other Revenue

	year 1	year 2
OTHER REVENUE	$ 16,577.04	$ 16,908.58
CAFETERIA SALES	$ -	$ -
GIFT SHOP SALES	$ 3,772.23	$ 3,847.67
VENDING SALES	$ 13,317.71	$ 13,584.06
COT RENTAL	$ -	$ -
OTHER RENTAL	$ 105,243.10	$ 107,347.96
MEDICAL TRANS.	$ 656.61	$ 669.74
INTEREST INCOME	$ (2,269.47)	$ (2,314.86)
MISCELLANEOUS INC(	$ 11,132.79	$ 11,355.44
SUPPLIES SOLD	$ -	$ -
	148,430	151,399

PROJECTED DATA CHART (Lithotripsy Only)

Give information for the two (2) years following completion of this proposal. The fiscal year begins in _____.

		Year 1	Year 2
A.	Utilization/Occupancy Data (Litho Treatments).	165	180
B.	Revenue from Services to Patients		
	1. Inpatient Services		$ -
	2. Outpatient Services	$ 1,540,707	$ 1,680,772
	3. Emergency Services	$ -	$ -
	4. Other Operating Revenue (Specify) _____		$ -
	Gross Operating Revenue	**$ 1,540,707**	**$ 1,680,772**
C.	Deductions from Operating Revenue		
	1. Contractual Adjustments	$ 941,055	$ 1,055,257
	2. Provisions for Charity Care	$ 48,723	$ 54,636
	3. Provisions for Bad Debt	$ 37,450	$ 41,994
	Total Deductions	**$ 1,027,227**	**$ 1,151,887**
NET OPERATING REVENUE		$ 513,480	$ 528,884
			$ -
D.	Operating Expenses		
	1. Salaries and Wages	$ 3,486	$ 3,803
	2. Physicians' Salaries and Wages		
	3. Supplies	$ 5,135	$ 5,289
	4. Taxes		
	5. Depreciation		
	6. Rent		
	7. Interest, other than Capital		
	8. Management Fees:		
	a. Fees to Affiliates		
	b. Fees to Non-Affiliates		
	9. Other Expenses	$ 396,000	$ 407,880
	Specify: _____		
	Total Operating Expenses	$ 404,620	$ 416,971
E.	Other Revenue (Expenses)--Net		
	Specify: _____		
NET OPERATING INCOME (LOSS)		$ 108,860	$ 111,913
F.	Capital Expenditures		
	1. Retirement of Principal		
	2. Interest		
	Total Capital Expenditures	$ -	$ -
NET OPERATING INCOME (LOSS)		$ 108,860	$ 111,913
LESS CAPITAL EXPENDITURES		$ -	$ -
NOI LESS CAPITAL EXPENDITURES		$ 108,860	$ 111,913

5. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.

Average Gross Charge:	$9,337.61
Average Deduction:	$6,225.61
Average Net Charge:	$3112.00

6. A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.

This is a proposed new service, so there are no current charges. The proposed charges are:

Description	HCPCS	Net Charge	Gross Charge
LITHOTRIPSY UNILATERAL	50590	$3,112.54	$9,337.62
BILATERAL LITHOTRIPSY	50590	$3,112.54	$9,337.62

This proposal will not impact existing patient charges.

B. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

Ther are no lithotripsy providers in the service area. Charges for lithotripsy servies in any adjoining areas are not available to the applicant. To the applicant's knowledge no new lithotripsy services have been approved recently enough that the comparison would be meaningful

Below are the average gross charges per procedure for lithotripsy treatments, from the HSDA Medical Equipment Registry.

Equipment Type	1st Quartile	Median	3rd Quartile
Lithotripter	$9,029.86	$12,783.82	$17,953.48

Source: HSDA Medical Equipment Registry - 1/7/2015

7. **Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness.**

   As reflected on the Projected Data Chart, the proposal is profitable in Year and thereafter.

8. **Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.**

   As reflected in the Projected Data Chart, financial viability will be achieved in Year 1.

9. **Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.**

   TH-LMC participates in the Medicare and TennCare programs. It contracts with all TennCare networks operating in the region. The estimated revenues and payor mixes for the lithotripsy program are reflected below:

Payor	Payor Mix	Net Revenue Year 1
Medicare:	59.5%	$305,521
TennCare:	17.6%	$90,372

10. **Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility-10.**

    The financials for TH-LMC are rolled up into the Consolidated financials of the parent company. A copy of the audited Consolidated Statements of Income and Consolidated Balance Sheets for Community Health Systems, Inc. and Subsidiaries is attached as Attachment C, II, Economic Feasibility 10.

11. **Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:**

    a. **A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.**

    No more cost effective alternatives were identified. The leased, part-time lithotripsy service arrangement calls for a fixed payment per procedure by the hospital to the mobile vendor. The hospital then bills the 3rd party payor. No construction or renovation of the hospital is required. This proposal require little or no out of pocket capital expenditure, and can be financially sustained through operating revenues of the program. .

    b. **The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.**

    As mentioned above, the is no construction hospital renovation required. No superior alternatives were identified, or are thought to exist.

(III.) CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

1. **List all existing health care providers (e.g., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.**

    - Team Health – Emergency Department physician coverage
    - Resource Anesthesia – CRNA Coverage Vendor
    - Innovative Pathologists – Pathology Vendor
    - Abercrombie – Radiology Vendor
    - Healogics – Wound Care Vendor
    - University of Tennessee Medical Center -- Transfer Agreement
    - Kentucky 1 Lithotripsy -- Mobile Lithotripsy Services Agreement

2. **Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition**

arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

This proposal will have a positive effect on the health care system. It will bring a needed health care service that is currently not available in the service area.

This proposal will have no negative effect on the health care system. There are no exiting providers of lithotripsy in the service area. No capital expenditure is required, so even if the service were to be utilized at a rate less than the projected volume, there would be no added cost to the health care system.

3. **Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.**

Staffing	Wage	Median Wage (TDLWD)*
1 RN	$27/hour	$28.19
1 surgical tech	$17/hour	$18.73
1 CRNA	$250/hour	$71.08

* Wages are stated as annual salaries on the TDLWD website. Those annual salaries were converted to an hourly rate based on 2,000 annual hours. In some cases the conversion may not result in an accurate hourly rate for part-time contractual services (e.g., the CRNA).

These positions are from the current hospital staff. No new staffing is required.

4. **Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Developmental Disabilities, and/or the Division of Mental Retardation Services licensing requirements.**

TH-LMC maintains compliance with all applicable regulatory and licensing requirements, including any staffing requirements. This proposal does not call for any additional staffing.

5. **Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing,**

admission privileges, quality assurance policies and programs, utilization review policies and programs, record keeping, and staff education.

The applicant so verifies.

6. **Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (*e.g.*, internships, residencies, etc.).**

   TH-LMC has training affiliations with the following educational institutions:

   - Lincoln Memorial University
   - South College
   - Appalachian College of Pharmacy
   - Tennessee Center for Applied Technology
   - University of Tennessee
   - Kaplan University
   - Mercer University
   - Anderson County Schools
   - King College
   - Roane State Community College
   - Southeast Kentucky Community & Technology College
   - Tennessee State
   - Virginia College
   - Creighton University
   - Brenau University

7. **(a) Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, the Division of Mental Retardation Services, and/or any applicable Medicare requirements.**

   The applicant so verifies.

   (b) Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.

   Licensure: Tennessee Board for Licensing Health Care Facilities

   Accreditation: The Joint Commission

   If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility.

TH-LMC is in good standing with al licensing and accrediting agencies.

A copy of the hospital license is attached as Attachment C, III, Orderly Development, 7.

8. **For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction.**

Since TH-LMC is Joint Commission accredited, a state licensure survey has not been performed in many years. The applicant could not locate a copy of any state survey.

All deficiencies of the latest TJC survey have been resolved and the Plan of Correction has been accepted. A copy of the most recent TJC survey is attached as Attachment C, III, Orderly Development, 8.

9. **Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.**

There are no settlements, judgments, or final orders entered in any state or country by a licensing agency or court against the professional license held by applicant. Neither CHS / Community Health Systems, Inc. nor Community Health Systems, Inc. holds professional licenses.

10. **Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project.**

There are no civil or criminal judgments for fraud or theft against applicant or CHS / Community Health Systems, Inc. which would jeopardize or negatively impact the funding of the project.

11. **If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.**

If the proposal is approved, the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.

PROOF OF PUBLICATION

Attach the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper as proof of the publication of the letter of intent.

The Notice of Intent was published in the Knoxville News Sentinel on August 9, 2015. A Publisher's Affidavit will be submitted on or before August 31, 2015.

DEVELOPMENT SCHEDULE

Tennessee Code Annotated § 68-11-1609(c) provides that a Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other projects) from the date of its issuance and after such time shall expire; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificates of Need for good cause shown. Subsequent to granting the Certificate of Need, the Agency may extend a Certificate of Need for a period upon application and good cause shown, accompanied by a non-refundable reasonable filing fee, as prescribed by rule. A Certificate of Need which has been extended shall expire at the end of the extended time period. The decision whether to grant such an extension is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

1. **Please complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.**

   A completed Project Completion Forecast Chart is attached.

2. **If the response to the preceding question indicates that the applicant does not anticipate completing the project within the period of validity as defined in the preceding paragraph, please state below any request for an extended schedule and document the "good cause" for such an extension.**

   The applicant does not request an extended period of validity at this time.

Form HF0004
Revised 05/03/04
Previous Forms are obsolete

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision date, as published in Rule 68-11-1609(c): November, 2015

Assuming the CON approval becomes the final agency action on that date; indicate the number of days **from the above agency decision date** to each phase of the completion forecast.

Phase	**DAYS REQUIRED**	**Anticipated Date (MONTH/YEAR)**
1. Architectural and engineering contract signed	_____	_____
2. Construction documents approved by the Tennessee Department of Health	_____	_____
3. Construction contract signed	_____	_____
4. Building permit secured	_____	_____
5. Site preparation completed	_____	_____
6. Building construction commenced	_____	_____
7. Construction 40% complete	_____	_____
8. Construction 80% complete	_____	_____
9. Construction 100% complete (approved for occupancy	_____	_____
10. *Issuance of license	N/A	N/A
11. *Initiation of service	30	December, 2015
12. Final Architectural Certification of Payment	_____	_____
13. Final Project Report Form (HF0055)	_____	_____

* **For projects that do NOT involve construction or renovation: Please complete items 10 and 11 only.**
Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

LIST OF ATTACHMENTS

Business Entity Detail

Available Entity Actions

File Annual Report (after 12/01/2015)

Certificate of Existence

Modify Mailing Address

Entity details cannot be edited. This detail reflects the current state of the filing in the system.

Return to the Business Information Search.

000660519: Limited Liability Company - Domestic

Printer Friendly Version

Name: Campbell County HMA, LLC

Status: Active
Formed in: TENNESSEE
Fiscal Year Close: December
Term of Duration: Perpetual
Principal Office: 4000 MERIDIAN BLVD FRANKLIN, TN 37067-6325 USA
Mailing Address: 4000 MERIDIAN BLVD FRANKLIN, TN 37067-6325 USA
AR Exempt: No
Managed By: Director Managed

Initial Filing Date: 06/10/2011
Delayed Effective Date:
AR Due Date: 04/01/2016
Inactive Date:
Obligated Member Entity: No
Number of Members: 1

Assumed Names | History | Registered Agent

Name	Status	Expires
Tennova LaFollette Medical Center Clinic - Jacksboro	Active	09/23/2016
Tennova LaFollette Medical Center Clinic	Active	09/08/2016
Tennova Infusion Center	Active	09/08/2016
Tennova LaFollette Health & Rehabilitation Center	Active	09/08/2016
Tennova LaFollette Outpatient Rehab Center	Active	09/08/2016
Tennova LaFollette Geriatric Psychiatric Unit	Active	09/08/2016
Tennova LaFollette Sleep Disorders Clinic	Active	09/08/2016
Irene and Howard H. Baker Cancer Treatment Center	Active	09/08/2016
Tennova Healthcare - LaFollette	Active	09/02/2016
Tennova Healthcare - LaFollette Medical Center	Active	09/02/2016

Attachment A, 4

COPY

AGREEMENT AND ASSIGNMENT OF LEASE

THIS AGREEMENT AND ASSIGNMENT OF LEASE ("*Agreement*") is made as of the 1ST day of OCTOBER, 2011, by and among THE CITY OF LAFOLLETTE, TENNESSEE, a city organized and existing as a governmental unit under the laws of the State of Tennessee, (the "Lessor"), ST. MARY'S MEDICAL CENTER OF CAMPBELL COUNTY, INC. (successor in interest to LAFOLLETTE MEDICAL CENTER, INC.), a Tennessee not-for-profit corporation, and MERCY HEALTH PARTNERS, INC. (successor in interest to St. Mary's Health System, Inc.), a Tennessee not-for-profit corporation being the sole member of LaFollette Medical Center, Inc., (collectively, the "*Assignor*") and CAMPBELL COUNTY HMA, LLC, a Tennessee limited liability company, (the "*Assignee*").

WITNESSETH:

WHEREAS, by that certain Lease and Purchase Option Agreement dated as of April 27, 2000, and that certain First Amendment to Lease Agreement which is anticipated in connection with this Assignment (collectively, the "*Lease*"), a copy of said Lease and all addenda, amendments and modifications thereof being attached hereto as EXHIBIT "A" and made a part hereof, Assignor leases that certain Leased Premises, as defined in the Lease, from the Lessor;

WHEREAS, Assignor desires to assign to Assignee and Assignee desires to accept from Assignor all of the right, title and interest of Assignor in and to the Lease and the Leased Premises; and

WHEREAS, Lessor desires to consent in all respects to the assignment of the Lease from Assignor to Assignee; and

WHEREAS, Assignore, Assignee and Lessor wish to agree in certain other respects as set forth herein;

NOW, THEREFORE, for and in consideration of the foregoing and for other good and valuable consideration and of the mutual agreements hereinafter set forth, the receipt and sufficiency of which are hereby acknowledged, Lessor, Assignor and Assignee stipulate, covenant and agree as follows:

1. ASSIGNMENT OF LEASE. Assignor does hereby presently and absolutely sell, assign, convey, transfer, set over and deliver to Assignee, effective as of the closing of the transactions pursuant to which Assignee and its affiliates will acquire substantially all of the assets of Assignee and its affiliates in East Tennessee (the "*Closing*"), currently anticipated to be October 1, 2011, (the date on which such Closing occurs, the "*Effective Date*"), all of Assignor's right, title and interest in and to the Lease and to the Leased Premises arising thereunder. Lessor hereby consents to the foregoing assignment in all respects and agrees to be bound thereby. The parties agree that the Effective Date will be deemed to have occurred, and the foregoing

Physician recruitment → anomalies salvia
or just recruitment expenses? What are we
allowed?

systems, facility renovations, new facilities, medical office space, and development of new services, quality improvement programs, physician recruitment and other capital expenditures at the Leased Premises or the Undeveloped Land. Any cause beyond Assignee's control that prevents or delays Assignee's performance of its obligations hereunder, including the acts and requirements of governmental authorities, acts of God, acts of war or terrorism, civil insurrection, strikes or unavailability of raw materials or supplies shall extend the Expenditure Period to the extent necessary for Assignee to meet its obligations after the cause of the delay has been removed, provided that Assignee shall have no obligations hereunder following the expiration of the term of the Lease. Assignee shall, upon Lessor's reasonable request (but not more frequently than annually) during the remaining term of the Lease (including any "Renewal Term" pursuant to Section 4.3(b) thereof), provide Lessor with a report as to its expenditures pursuant to this Section.

7. **FEASIBILITY & ECONOMIC STUDY.** Assignee at its sole cost and expense, agrees to conduct a feasibility and economic study to determine the economic viability of additional healthcare facilities by an independent third party selected by Assignee, and approved by Lessor (which approval will not be unreasonably withheld).

Feasibility Study

8. **ESCROW.** Assignee shall establish an escrow account and fund THREE HUNDRED THOUSAND ($300,000.00) dollars per year for the remainder of the Lease, including any "Renewal Term" pursuant to Section 4.3(b) thereof, (up to an aggregate of TWO MILLION FOUR HUNDRED THOUSAND DOLLARS ($2,400,000.00)) for the purpose of funding the construction of additional healthcare facilities, if Assignee elects to construct such facilities. In the event, Assignee elects not to construct additional healthcare facilities during the remaining term of the Lease, the escrowed funds (and all interest accrued thereon) will be released to Lessor upon the termination of the Lease. In the event, Assignee elects in its sole discretion to construct additional healthcare facilities during the remaining term of the Lease (including any "Renewal Term" pursuant to Section 4.3(b) thereof), Lessor agrees that the escrowed funds (and all interest accrued thereon) will be released to Assignee and be available for use in funding the costs of constructing or equipping such healthcare facilities.

C.I.P.

9. **CHARITABLE CONTRIBUTION.** Upon the Effective Date, Assignor will make an unrestricted donation to the Lessor or its designee in the amount of ONE HUNDRED AND TWENTY FIVE THOUSAND DOLLARS ($125,000.00) to be used by Lessor or its designee for appropriate charitable purposes. In addition, Assignee will make an unrestricted donation to the Lessor or its designee to be used by Lessor for appropriate purposes in the amount of ONE HUNDRED AND TWENTY FIVE THOUSAND ($125,000.00) Dollars and, in Assignee's sole discretion, up to an additional unrestricted donation to the Lessor or its designee to be used by Lessor for appropriate purposes in the amount of ONE HUNDRED AND TWENTY FIVE THOUSAND ($125,000.00), following the determination of any property tax assessment with respect to the Leased Premises.

already been made

assignment and the other transactions described herein will become effective only upon the Closing.

2. **ASSUMPTION.** Assignee hereby assumes all of Assignor's obligations as lessee under the Lease with regard to the Leased Premises, from and after the Effective Date but not prior thereto.

3. **GUARANTY.** Notwithstanding the deletion of the Mercy Health Partners, Inc. guarantee in the First Amendment to Lease Agreement, Assignee agrees to provide a guarantee of the Lease by Knoxville HMA Holdings, LLC in the form attached hereto as **EXHIBIT "B"**.

4. **UNDEVELOPED LAND.** For and in consideration of the sum of one dollar ($1.00), Assignor hereby agrees to convey to Lessor all of its right title and interest in and to the undeveloped land described on **EXHIBIT "C"** attached hereto (the "**Undeveloped Land**"), which conveyance will occur on the Effective Date or as soon thereafter as practicable. Assignee is a third party beneficiary of Assignor's agreement to convey the Undeveloped Land to Lessor and shall have the right to enforce such obligation. Lessor acknowledges that during the remaining term of the Lease (including any "Renewal Term" pursuant to Section 4.3(b) thereof) the Undeveloped Land will be used solely and exclusively by Assignee, and solely for the construction and operation of healthcare facilities should Assignee elect to construct healthcare facilities thereon. If Assignee elects to construct healthcare facilities on the Undeveloped Land during the term of the Lease, Lessor agrees to transfer to Assignee, upon Assignee's request, for no consideration, fee title constituting all of Lessor's right, title and interest in and to the Undeveloped Land, free and clear of encumbrances, for the purpose of constructing and operating healthcare facilities. → healthcare facility, not necessarily a hospital

5. **ACCELERATED RENTAL PAYMENT.** Upon the Effective Date, Assignee shall pay to Lessor a lump sum rental payment (calculated on a net present value basis) in the amount of FIVE HUNDRED TEN THOUSAND DOLLARS ($510,000.00), which payment will, notwithstanding any contrary provision of Article 5 of the Lease or any other provision of the Lease, satisfy any and all rental payments owed, owing or that may become due at any time during the remaining term of the Lease (including any "Renewal Term" pursuant to Section 4.3(b) of the Lease). The parties expressly acknowledge that the foregoing provisions expressly modify the Lease in accordance with Section 12.5 thereof. In addition, Assignor shall direct the release of TWO HUNDRED THOUSAND ($200,000.00) dollars of currently escrowed rental payments for the benefit of Lessor.

6. **CAPITAL COMMITMENT.** During the remaining term of the Lease (including any "Renewal Term" pursuant to Section 4.3(b) thereof) (the "***Expenditure Period***"), Assignee commits to fund at least TWELVE MILLION DOLLARS ($12,000,000.00) in the aggregate in capital expenditures with respect to the Leased Premises or the Undeveloped Land. The capital expenditures made by Assignee during the Expenditure Period may include, at Assignee's election, expenditures for new equipment, equipment replacement, information

10. INDEMNIFICATION. Assignor hereby defends, indemnifies and holds Assignee harmless from and against any and all loss, cost, damage, expense (including reasonable attorneys' fees), liability, claim or cause of action incurred by Assignee as a result of claims brought against Assignee, as Assignor's successor-in-interest to the Lease, arising prior to the Effective Date hereof from, in connection with, or in any way relating to the Lease. Assignee hereby agrees to defend, indemnify and hold Assignor harmless from and against any and all loss, cost, damage, expense (including reasonable attorneys' fees), liability, claim or cause of action incurred by Assignor as a result of claims brought against Assignor by reason of Assignee's failure to perform the obligations set forth in the Lease and assumed hereunder by Assignee from and after the Effective Date.

11. BINDING EFFECT. The covenants and agreements herein contained shall bind and inure to the benefit of and be binding upon each party hereto and its respective heirs, legal representatives, successors and assigns. The foregoing provisions shall be deemed for all purposes to modify the Lease in accordance with Section 12.5 thereof.

THE REMAINDER OF THIS PAGE IS INTENTIONALLY BLANK

IN WITNESS WHEREOF, duly authorized representatives of the parties hereto have executed this Agreement and Assignment of Lease as of the day and year first above written.

ASSIGNOR:

ST. MARY'S MEDICAL CENTER OF CAMPBELL COUNTY, INC.,
(successor in interest to LaFollette Medical Center, Inc.)

By: _____
Name: Jeffrey A. Ashin
Title: President and CEO

MERCY HEALTH PARTNERS, INC.
(successor in interest to St. Mary's Health System, Inc.)

By: _____
Name: Jeffrey A. Ashin
Title: President and CEO

ASSIGNEE:

CAMPBELL COUNTY HMA, LLC

By: _____
Name: Timothy R. Parry
Title: Senior Vice President

LESSOR:

THE CITY OF LAFOLLETTE, TENNESSEE

By: _____
Name: Michael R. Stinnett
Title: Mayor

CITY OF LaFOLLETTE, TENNESSEE

to

LaFOLLETTE MEDICAL CENTER, INC.

LEASE AND PURCHASE OPTION AGREEMENT

Dated as of April 27, 2000

Relating to LaFollette Medical Center

Prepared by:

Robertson, Ingram & Overbey
The Farragut Building
530 South Gay Street, Suite 802
Knoxville, Tennessee 37902-1537
865.522.2717

Recorded in the Office of
Register of Deeds
Campbell County, Tennessee
as Instrument No. _____ in
Book _____ at Page _____

TABLE OF CONTENTS

LEASE AND PURCHASE OPTION AGREEMENT

This Lease and Purchase Option Agreement ("Agreement") is made and entered into as of the 27th day of April, 2000, by and between THE CITY OF LaFOLLETTE, TENNESSEE (the "City"), a municipality organized and existing as a governmental unit under the laws of the State of Tennessee, and having its principal seat of government in LaFollette, Tennessee, and LaFOLLETTE MEDICAL CENTER, INC., a not-for-profit corporation organized and existing under the laws of the State of Tennessee (the "Lessee"), and ST. MARY'S HEALTH SYSTEM, INC., a not-for-profit corporation organized and existing under the laws of the State of Tennessee and sole member of Lessee ("St. Mary's").

Recitals

1. The City owns a sixty-six (66) bed hospital facility, a ninety-eight (98) bed nursing home, a home health agency, and a medical office building, all of which are located in the City and are collectively known as LaFollette Medical Center (the "Hospital") serving primarily the medical needs of residents of the City and Campbell County.

2. The City Council of the City (the "Governing Body") has determined that (a) certain improvements, program developments and other activities related to the future of the Hospital are necessary to (i) insure the long-term viability of the Hospital as a modern, up-to-date health care facility, (ii) assure residents of the City and County convenient access to affordable, quality health care, and (iii) strengthen strategic aspects of delivery and administration of managed care products and services in the community, and (b) the best way to accomplish such objectives is by means of this Agreement.

3. Lessee is a duly constituted and empowered Tennessee not-for-profit corporation, organized for charitable purposes, and, prior to the Commencement Date, as hereinafter defined, will have applied to the Internal Revenue Service to be recognized as an organization exempt from federal income taxation under Section 501(a) of the Internal Revenue Code of 1986, as amended (the "Code"), by virtue of the provisions of Section 501(c)(3) of the Code.

4. St. Mary's is a duly constituted and empowered Tennessee not-for-profit corporation, organized for charitable purposes, and is recognized by the Internal Revenue Service as an organization exempt from federal income taxation under Section 501(a) of the Internal Revenue Code of 1986, as amended (the "Code"), by virtue of the provisions of Section 501(c)(3) of the Code, which understands and has experience in the delivery of health care in East Tennessee, and is the sole member of Lessee.

5. The City, pursuant to its powers under the City Charter and the Constitution and the laws of the State of Tennessee, including ordinances, resolutions and other legislative proceedings of the Governing Body, has the authority and desires to exercise such powers by leasing with an option to purchase the Leased Premises, as herein defined, to Lessee, on the terms and conditions herein set forth.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual promises and agreements among the City, the Lessee, and St. Mary's hereinafter set forth, it is hereby agreed as follows:

Article I
Definitions

Section 1.1. Definitions. The following terms are defined terms under this Agreement and shall have the following meanings given to them, unless the context and use clearly indicates a different intent and meaning:

"Agreement" means this Lease and Purchase Option Agreement and any future amendments and supplements hereto.

"Authorized Lessee Representative" means the person at any relevant time designated to act on behalf of the Lessee by written certificate furnished to the City containing the specimen signature of such person and signed on behalf of the Lessee by its President or other officer authorized by its Board of Directors or members. Such certificate may designate an alternate or alternates.

"Authorized City Representative" means the person at any relevant time designated to act on behalf of the City by written certificate furnished to the Lessee containing the specimen signature of such person and signed by the Mayor. Such certificate may designate an alternate or alternates. In this Agreement, wherein reference is to a "direction of the City," said direction shall be in writing and signed by an Authorized City Representative.

"City" means the City of LaFollette, Tennessee, a municipality organized and existing pursuant to the City Charter.

"City Charter" means Chapter 161 of the Private Acts of 1897 of the State of Tennessee, as amended.

"City Recorder" means, at any relevant time, the duly appointed and incumbent City Recorder of the City or such other public official who, under applicable law, has succeeded to the office of or is then exercising the powers of such City Recorder.

"Code" means the federal Internal Revenue Code of 1986, as amended, or the provisions of any successor code with respect to the federal taxation of income of individuals, corporations and other organizations, as applicable.

"Commencement Date" means the time and date the Lease Term commences, being 12:01 a.m., July 1, 2000.

"County" means Campbell County, Tennessee.

"Current Obligations" means only the following items set out under the heading of "Current Obligations" on Exhibit C, hereto: accounts payable, other accrued expenses, accrued compensation benefits, and estimated third-party settlements.

"Ethical and Religious Directives" means the Ethical and Religious Directives for Catholic Health Care Services as promulgated by the National Conference of Catholic Bishops as adopted in the archdiocese or diocese in which the Hospital is located. In the event that the National Conference of Catholic Bishops shall cease to exist, "Ethical and Religious Directives" shall mean such similar directives promulgated by its successor organization or by such organization then exercising its powers and duties, and in the event such archdiocese or diocese shall cease to exist so that there is not then an individual bearing the title Archbishop or Bishop of such archdiocese or diocese, such term shall mean the Ethical and Religious Directives adopted by the individual or organization then exercising the power, duties and authority of such Archbishop or Bishop.

"Excluded Assets" means the Hospital's assets shown on its balance sheet as of March 31, 2000, as "other receivables" and "assets limited as to use by Board ~~for self-insurance~~," in the amounts set out in Exhibit D, attached hereto and herein incorporated by reference, as the same shall be adjusted by Coulter & Justus to reflect changes therein from March 31, 2000, to the Commencement Date, which adjusted amount the parties agree represents the Excluded Assets of the existing LaFollette Medical Center as of the Commencement Date.

"Fiscal Year" means the period in any year commencing on January 1 and ending on December 31 of such year.

"Governing Body" or *"Governing Bodies"* means, with reference to the City, its City Council or such other successor body as may be provided by law and, with reference to the Lessee and St. Mary's, their respective Boards of Directors and members.

"Health Care Facility" means a facility for the delivery of health care services, including but not necessarily limited to acute care of in-patients, which provides, by and under the supervision of physicians, medical diagnosis and treatment, both surgical and non-surgical, over a continuous 24-hour period, seven days a week, to persons injured, sick or disabled, as well as out-patient and emergency room medical services.

"Hospital" means LaFollette Medical Center, including any and all subordinate and related facilities, including, without limitation, LaFollette Nursing Home, LaFollette Home Health, and LaFollette Medical Office Building, located on the Leased Land.

"Hospital Bonds" means the City of LaFollette, Tennessee, General Obligation Nursing Home Refunding Bonds, 1993 Series, bearing interest at rates from 2.5% to 5.1% and due in annual installments through March 2011 plus semi-annual interest payments.

"Hospital Equipment Leases" means the leases of equipment for the Hospital to (i) FINOVA Gov't Finance, Inc., (ii) Pitney Bowes Credit Corp., (iii) Panasonic Credit Company, (iv)

Datascope Corp., and (v) GE Medical Systems, which equipment leases and the rental obligations thereunder are reflected in Exhibits E-1, E-2, E-3, E-4, and E-5, respectively.

"Hospital Notes" means (i) the City of LaFollette, Tennessee, capital outlay note payable, due in semi-annual installments of $39,517, including interest at 5.5%, through July 2011 for construction and equipping of the Independent Living Center, and (ii) the noninterest bearing term loan for the purchase dietary equipment, which loan had an outstanding principal balance of $31,722 as of June 30, 1999, and is payable in monthly installments of $961 through February 2002.

"Lease Term" or *"Term"* means the duration of the leasehold estates created in this Agreement, including any renewals thereof.

"Lease Year" means initially the time period commencing on the Commencement Date of this Agreement and ending at the end of the day immediately preceding the first annual anniversary of the Commencement Date, and thereafter, the period of time commencing on each annual anniversary of the Commencement Date and ending at the end of the day immediately preceding the next succeeding annual anniversary of the Commencement Date.

"Leased Equipment" means those items of equipment and related property as described in Exhibit B hereto and City's leasehold interest under the Hospital Equipment Leases, together with all items of equipment and related property installed or placed in or on the Leased Premises by Lessee as replacement or additional equipment.

"Leased Land" means the real estate and interests in real estate described in Exhibit A, which is attached hereto and by reference made a part hereof, together with the buildings, additions, improvements, fixtures, and facilities thereon and appurtenances thereto.

"Leased Premises" means the Leased Land and the Leased Equipment.

"Lessee" means LaFollette Medical Center, Inc.

"Lessee's Board of Directors" means the Board of Directors of LaFollette Medical Center, Inc.

"Mayor" means, at any relevant time, the duly elected and incumbent Mayor of the City or such other public official who, under applicable law, has succeeded to the office of or is then exercising the powers of such Mayor.

"Net Working Capital" means the amount specified in Exhibit C, attached hereto and herein incorporated by reference, as the same shall be adjusted as provided in Section 3.4, below, to reflect changes therein from March 31, 2000, to the Commencement Date, which adjusted amount the parties agree represents the net working capital of the existing LaFollette Medical Center as of the Commencement Date.

"Permitted Encumbrances" means, as of any particular time (i) this Agreement, (ii) easements of record as of the date hereof, (iii) mineral rights that will not materially affect, interfere with or impair the use of the Leased Premises by Lessee under this Agreement, and (iv) such minor defects, irregularities, encumbrances, easements, rights-of-way and clouds on title as normally exist with respect to properties similar in character to the Leased Premises so long as no one or more of them, alone or in combination, materially affects, impairs or interferes with Lessee's use of the Leased Premises for the purposes hereby contemplated.

"Replacement Hospital" means a Health Care Facility, including the property on which it is situated, and those subordinate and related facilities, furnishings, fixtures and equipment that Lessee's Board of Directors deems adequate to meet the health care needs of the City and the County.

"St. Mary's" means St. Mary's Health System, Inc., the sole member of Lessee.

Section 1.2. Alternative Forms of Defined Terms. The use of the singular form of any word herein shall also include the plural form and vice versa. The use of the neuter form of any word herein shall also include the masculine and feminine forms, and the masculine form shall include the feminine and neuter forms and vice versa.

ARTICLE II
Representations

Section 2.1. Representations by the City. The City makes the following representations as the basis of the undertakings on its part herein contained:

(a) The City is duly incorporated and validly existing as a municipality and public corporation under the provisions of the City Charter.

(b) Under the provisions of the City Charter, Constitution, and applicable laws of the State of Tennessee, the City has the power and authority to enter into this Agreement, including the option to purchase, and the transactions hereby contemplated and to carry out and perform its obligations hereunder.

(c) The Governing Body of the City has, by all necessary and appropriate proceedings, approved the form and substance of this Agreement and has duly authorized its execution, delivery and performance by the City. Such proceedings are (i) valid and in accordance with all applicable laws, including, without limitation the "Sunshine Law," and (ii) are either not subject to veto or appeal or the time therefor has elapsed and such proceedings have not been repealed, amended or supplemented as of the date hereof.

(d) Upon its due execution and delivery by all other parties hereto, this Agreement will be a valid and binding obligation of the City, enforceable in accordance with its

terms, subject only to bankruptcy and other similar laws affecting the rights of creditors and the exercise of judicial discretion in appropriate cases.

(e) Neither the City's execution and delivery of this Agreement nor the City's performance of its obligations under this Agreement (i) violates any provision of the Constitution or laws of the State of Tennessee or the City Charter or (ii) conflicts with or violates, in any material respect, any representation, warranty, covenant, agreement or other obligation binding upon the City or applicable to the Leased Property or Leased Equipment.

(f) There are no judicial or administrative proceedings pending or, to the best of the City's knowledge, threatened, challenging directly or indirectly (i) the validity of the proceedings by the City's Governing Body authorizing the City's execution, delivery and performance of this Agreement, (ii) the validity of this Agreement, or (iii) the City's power and authority to perform its obligations under this Agreement in accordance with its provisions.

(g) Except as disclosed on Exhibit A, the City owns the Leased Land in fee simple with title thereto unencumbered except by Permitted Encumbrances.

(h) Except as disclosed on Exhibit B, City has absolute unencumbered ownership of the Leased Equipment.

(i) The Hospital Bonds and Hospital Notes are the only outstanding debt obligations of the City with respect to the Leased Premises, including, without limitation, the Hospital.

(j) The Hospital Equipment Leases are the only outstanding lease obligations of the City with respect to the Leased Premises, including, without limitation, the Hospital.

Section 2.2. Representations by the Lessee. Lessee makes the following representations as the basis for the undertakings on its part herein contained:

(a) The Lessee (i) is a nonprofit public benefit corporation organized and existing under the laws of the State of Tennessee and exempt from federal income taxation under Section 501(a) of the Code as an organization described in Section 501(c)(3) of the Code; (ii) will, as of the Commencement Date, have applied for a determination letter from the Internal Revenue Service to such effect; (iii) is not aware of any facts or circumstances that could cause a denial of that letter; (iv) will comply with all terms and conditions of such determination letter when and as received; and, (v) has not taken and will not take any actions that would jeopardize its status as an organization described in Section 501(c)(3) of the Code exempt from taxation under Section 501(a) of the Code.

(b) The Lessee has the power to enter into this Agreement and carry out its obligations hereunder and, by all proper corporate action, has been duly authorized to enter into, execute and deliver this Agreement, subject to the Lessee's obtaining authorization from applicable regulatory authorities (i) to use the Hospital's existing Medicare provider number or the Lessee's securing a new provider number and (ii) to operate the Hospital under the City's existing license or Lessee's securing a new license to operate the Hospital.

(c) Upon its due execution and delivery by all other parties hereto, this Agreement will be a valid and binding obligation of the Lessee, enforceable in accordance with its terms, subject only to bankruptcy and other similar laws affecting the rights of creditors and the exercise of judicial discretion in appropriate cases.

(d) Neither the Lessee's execution and delivery of this Agreement nor Lessee's performance of its obligations under this Agreement (i) violates any provision of the Constitution or laws of the State of Tennessee or (ii) conflicts with or violate, in any material respects, any representation, warranty, covenant, agreement or other obligation of the Lessee.

(e) There are no judicial or administrative proceedings pending or, to the best of the Lessee's knowledge, threatened, challenging directly or indirectly (i) the validity of the proceedings of the Lessee authorizing the execution, delivery and performance of this Agreement, (ii) the validity of this Agreement, or (iii) the Lessee's power and authority to perform its obligations under this Agreement in accordance with its provisions.

(f) The Lessee's Charter and Bylaws presently conform and, during the term of this Agreement, they and any superseding document by whatever name designated shall continue to conform to the provisions of this Agreement and to those provisions applicable:

(1) for exemption from federal income taxation as a nonprofit corporation exempt from federal income taxation under Section 501(a) of the Code by virtue of the provisions of Section 501(c)(3) of the Code; and,

(2) for a duly constituted and empowered Tennessee corporation, organized for charitable purposes and not for profit.

Section 2.3 Representations by St. Mary's. St. Mary's makes the following representations as the basis of the undertakings on its part herein contained:

(a) St. Mary's (i) is a nonprofit public benefit corporation organized and existing under the laws of the State of Tennessee and exempt from federal income taxation under Section 501(a) of the Code as an organization described in Section 501(c)(3) of the Code; (ii) has received a determination letter from the Internal Revenue Service to

such effect; (iii) is not aware of any facts or circumstances that could cause a denial of that letter; (iv) will comply with all terms and conditions of such determination letter when and as received; and, (v) has not taken and will not take any actions that would jeopardize its status as an organization described in Section 501(c)(3) of the Code exempt from taxation under Section 501(a) of the Code.

(b) St. Mary's has the power to enter into this Agreement and carry out its obligations hereunder and, by all proper corporate action, has been duly authorized to enter into, execute and deliver this Agreement, subject to the Lessee's obtaining authorization from applicable regulatory authorities (i) to use the Hospital's existing Medicare provider number or the Lessee's securing a new provider number and (ii) to operate the Hospital under the City's existing license or Lessee's securing a new license to operate the Hospital.

(c) Upon its due execution and delivery by all other parties hereto, this Agreement will be a valid and binding obligation of St. Mary's, enforceable in accordance with its terms, subject only to bankruptcy and other similar laws affecting the rights of creditors and the exercise of judicial discretion in appropriate cases.

(d) Neither St. Mary's execution and delivery of this Agreement nor its performance of its obligations under this Agreement (i) violates any provision of the Constitution or laws of the State of Tennessee or (ii) conflicts with or violate, in any material respects, any representation, warranty, covenant, agreement or other obligation of St. Mary's.

(e) There are no judicial or administrative proceedings pending or, to the best of St. Mary's knowledge, threatened, challenging directly or indirectly (i) the validity of the proceedings of St. Mary's authorizing the execution, delivery and performance of this Agreement, (ii) the validity of this Agreement, or (iii) St. Mary's power and authority to perform its obligations under this Agreement in accordance with its provisions.

(f) St. Mary's Charter and Bylaws presently conform and, during the term of this Agreement, they and any superseding document by whatever name designated shall continue to conform to those provisions applicable:

(1) for exemption from federal income taxation as a nonprofit corporation exempt from federal income taxation under Section 501(a) of the Code by virtue of the provisions of Section 501(c)(3) of the Code; and,

(2) for a duly constituted and empowered Tennessee corporation, organized for charitable purposes and not for profit.

ARTICLE III
Demising Clause; Exclusive Option; Title Insurance; and, Net Working Capital

Section 3.1. Demise of the Project. In consideration of and subject to the rentals and other terms and conditions herein specified, and otherwise in accordance with the provisions of this Agreement, City hereby demises and leases the Leased Premises to Lessee.

Section 3.2. Exclusive Purchase Option. City grants to Lessee the exclusive right and option to purchase the Leased Premises, together with any and all easements and rights-of-way City owns in conjunction therewith. The purchase option hereby granted is exercisable by Lessee upon the earlier occurrence of the following events:

(i) the completion by Lessee of the Replacement Hospital; or,

(ii) the nineteenth (19th) anniversary of the Commencement Date of this Agreement.

Lessee may exercise its purchase option granted herein by Lessee's giving written notice thereof, in accordance with Article XI, below, to the City upon either of the following events, whichever is applicable:

(a) within thirty (30) days of the completion of the Replacement Hospital; or,

(b) at anytime following the nineteenth (19th) anniversary of the Commencement Date but not later than one hundred twenty (120) days after receipt of written notice from the City of the expiration of the Lease Term or one hundred twenty days (120) of the twentieth (20th) anniversary of the Lease, whichever is later.

The purchase price for the Leased Premises shall be One Dollar ($1.00). Closing of the purchase shall take place in LaFollette, Tennessee, within thirty (30) days of either the effective date of Lessee's notice, if the option is exercised upon completion of the Replacement Hospital, or the day immediately preceding the twentieth (20th) anniversary of the Commencement Date, if the option is exercised following the nineteenth (19th) anniversary of the Commencement Date. At closing, all documents necessary for conveyance of the Leased Premises to Lessee shall be executed and delivered by City, all adjustments shall be made, and the purchase price shall be paid by Lessee. City shall execute and deliver all instruments reasonably deemed necessary by Lessee to accomplish this transaction. City shall convey good and marketable fee simple title of the Leased Premises to Lessee by general warranty deed, qualifying for the issuance of a standard ALTA title insurance policy, free and clear of all liens and encumbrances, except only the lien for real estate taxes, if any, for the year in which closing occurs which shall be prorated to date of closing and assumed by Lessee.

Section 3.3. Title Insurance or Opinion. Lessee may, at its expense, obtain a policy or policies of title insurance in such amount as Lessee deems appropriate in its sole discretion or an opinion of counsel acceptable to Lessee that the City has good and merchantable title to the Leased

Premises subject only to Permitted Encumbrances. City shall cooperate fully with Lessee with respect to Lessee's obtaining such title insurance or opinion of counsel.

Section 3.4. Net Working Capital.

(a) Purchase of Net Working Capital. The City and Lessee agree that, on the Commencement Date, Lessee shall purchase from City the Net Working Capital of the Hospital, and City shall transfer to Lessee ownership of the Net Working Capital of the Hospital. Net Working Capital shall not include the Excluded Assets as set out in Exhibit D.

(b) Computation of Net Working Capital. Attached hereto as Exhibit C is the net working capital of the Hospital as of March 31, 2000, as reflected in the Hospital's most recent financial statements. The parties agree that the amount of net working capital reflected in Exhibit C shall be adjusted to reflect changes therein from March 31, 2000, to the Commencement Date, and the Net Working Capital transferred to Lessee and the amount paid by Lessee to City therefor shall be the amount as presented in the audited short-period financial statements of the Hospital as of June 30, 2000, as prepared by Coulter & Justus, P.C., CPA's. On the Commencement Date, Lessee shall pay to the City eighty (80%) percent of the Net Working Capital as reflected on Exhibit C. Within sixty (60) days of the Commencement Date, Coulter & Justus, P.C., shall furnish the parties hereto with the audited short-period financial statements as of June 30, 2000. Within thirty (30) days thereof, either party may submit to the other a detailed statement setting out any objection to the calculation of Net Working Capital. The City and Lessee shall, in good faith, use reasonable efforts to resolve any objection and to reach an agreement as to the amount of Net Working Capital. Within ten (10) days after the parties agree upon the amount of Net Working Capital, if the amount of Net Working Capital is greater than the amount paid by Lessee on the Commencement Date, Lessee shall pay the City the difference therein or if the amount of Net Working Capital is less than the amount by Lessee on the Commencement Date, the City shall repay the difference to the Lessee. In the event the parties are unable to agree as to the amount of Net Working Capital, they shall select an independent accounting firm, whose determination as to the amount of Net Working Capital shall be binding.

(c) Lessee's Assumption of Current Obligations. Upon the Commencement Date, Lessee shall assume and satisfy when due the Current Obligations. Such assumption shall be evidenced by a written instrument executed by Lessee, which instrument shall be in substantially the form and substance as Exhibit F, attached hereto.

(d) Pension Plan Assets. The parties agree that the Net Working Capital of the Hospital shall not be deemed to include the assets held by the City for the

benefit of its employees' Section 403(b) pension plan, which assets and any and all related liabilities shall, on the Commencement Date, be transferred and delivered by the City to the Lessee for the benefit of the Hospital's employees.

ARTICLE IV

Effective and Commencement Dates; Delivery and Acceptance of Possession; Lease Term; Surrender of Possession; and, Operation of Leased Premises by Lessee

Section 4.1. Effective Date. This Agreement shall become effective upon its execution on behalf of the City, Lessee, and St. Mary's.

Section 4.2. Delivery and Acceptance of Possession. City shall deliver possession of the Leased Premises to Lessee and the Lease Term shall commence at 12:01 a.m., July 1, 2000 (the "Commencement Date"), and Lessee shall accept possession of the Leased Premises upon such delivery.

Section 4.3. Lease Term.

(a) Initial Term. This Agreement shall have an initial Lease Term beginning on the Commencement Date and ending at the end of the day immediately preceding the tenth (10th) anniversary of the Commencement Date (the "Initial Term").

(b) Renewal Terms. Lessee shall also have the option to extend the Lease Term for two (2) additional terms of five (5) years each (each a "Renewal Term"). The Lessee may exercise its option to extend the Agreement for the first Renewal Term by giving written notice thereof to the City at least one (1) calendar year prior to the expiration of the Initial Term or within ninety (90) days of receipt of written notice from the City advising Lessee that the initial Lease Term will expire, whichever is later, and its option to extend the Agreement for the second Renewal Term by giving written notice thereof to the City at least one (1) calendar year prior to the expiration of the first Renewal Term of this Agreement or within ninety (90) days of receipt of written notice from the City advising Lessee that the first Renewal Lease Term will expire, whichever is later.

Anything in this Agreement to the contrary notwithstanding, this Agreement will terminate as of the closing of Lessee's purchase of the Lease Premises pursuant to the purchase option granted in Section 3.2, above.

Section 4.4. Surrender of Possession Upon Expiration or Termination. Upon the expiration or termination of this Agreement without Lessee's having exercised its exclusive option to purchase the Leased Premises, as provided in Section 3.2, above, Lessee shall promptly surrender

possession of the Leased Premises to the City in as good condition and state of repair as on the Commencement Date excepting, however, reasonable use, ordinary wear and tear, taking by condemnation, eminent domain or other process, and destruction or damage by fire or other unavoidable casualty, failing which the City may restore the Leased Premises to such condition and state of repair and the Lessee shall pay the cost of such restoration. In the event, however, that the City shall permit the Lessee to hold over after expiration of the Lease Term, such holding over shall constitute a tenancy from year to year only and shall not be considered as a renewal or extension of this Agreement; and, during such year-to-year tenancy, the Lessee shall pay the monthly rate of rental in effect immediately prior to the expiration of such term on the same payment schedule as provided for herein; and for the period of such tenancy, the Lessee shall be bound by all of the provisions of this Agreement insofar as, and to the extent that, the same may be pertinent.

Section 4.5. Operation of Leased Premises by Lessee. The parties hereto acknowledge that the operation of the Leased Premises by Lessee in accordance with the Ethical and Religious Directives is a matter of conscience to the Lessee. It is the intent of the parties that neither this Agreement nor any part hereof shall be construed to require the Lessee to violate the Ethical and Religious Directives in its operations and all parts of this Agreement must be interpreted in a manner that is consistent with the Ethical and Religious Directives; provided, however, that nothing in this section is intended to modify the requirement that the Lessee make payments specified in Article V hereof.

Article V
Rent and Additional Consideration

Section 5.1. Rents Payable. Lessee shall pay as rent each and every of the following enumerated items, with the time that payment of each such item of rent is due being as follows:

(a) Prepaid Basic Rent. On or before the Commencement Date, Lessee shall pay to the City the sum Five Million Two Hundred Fifty Thousand Dollars ($5,250,000) as prepaid rent to cover all rental payments due during the Initial Term of this Agreement. From such payment, the City shall cause to be satisfied any and all indebtedness, other than Current Obligations, as to the Leased Premises, including without limitation the Hospital Notes and Hospital Bonds, such that any and all liabilities of the City with respect to the Hospital and of Hospital existing as of the Commencement Date are paid and satisfied, excepting only the Hospital Equipment Leases and Current Obligations.

(b) Rent With Respect to Renewal Terms.

(i) During the first five (5) year Renewal Term, rental payments shall be One Hundred Thousand Dollars ($100,000.00) per year payable to the City on or before July 1 of each year during the Renewal Term. During the second five (5) year first Renewal Term, rental payments shall be Fifty Thousand Dollars

($50,000.00) per year payable to the City on or before July 1 of each year during the second Renewal Term.

(ii) All rental payments paid by Lessee to City during any Renewal Term shall be held in an mutually agreeable escrow account until the expiration or termination of this Agreement. If at the time of such expiration or termination Lessee has completed construction of the Replacement Hospital, all such rental payments, together with all interest earned thereon, shall be paid to Lessee upon the opening of the Replacement Hospital; otherwise, all such funds shall be paid to the City.

(c) Rent With Respect to Hospital Equipment Leases. To the lessor of each Hospital Equipment Lease, an amount which is sufficient to pay each rental payment on the Hospital Equipment Leases on each rental payment due date; provided, however, to the extent that the period for which such rental is payable on any Hospital Equipment Lease begins before or ends after the term of this Agreement, then such payments by Lessee shall be prorated based upon the actual number of lease days elapsed in the rental computation period divided by the total number of days in the applicable rental computation period. In the event Lessee exercises the exclusive purchase option set out in Section 3.2, above, and any Hospital Equipment Leases remain in effect as of the closing of said purchase, Lessee agrees to assume such Hospital Equipment Leases as may be in effect at the time of said closing.

Section 5.2. Additional Consideration. As additional consideration, Lessee shall:

(a) Prior to January 1, 2004, develop and produce a feasibility study to determine the need for and economic viability of a Replacement Hospital. Lessee agrees to retain the services of an independent consultant, with national or regional expertise in conducting such feasibility studies in the field of health care, to assist in the development and production of said feasibility study. Such consultant shall be selected by the Governing Body of the City from a list of qualified consultants provided by Lessee. If, in Lessee's sole judgment, the feasibility study indicates that a Replacement Hospital is needed and would be an economically viable project, Lessee shall, subject to the approval of its sole member, use all reasonable efforts to design, seek necessary approvals for, construct, and equip the Replacement Hospital. The City shall cooperate as requested and shall actively support Lessee's efforts to secure the necessary approvals for the Replacement Hospital, including, without limitation, approval of an application for a Certificate of Need from the Tennessee Health Facilities Commission and reasonably requested changes in zoning, variances in zoning, and any other land use restrictions. The foregoing notwithstanding, nothing herein shall be construed to require the Lessee to pursue construction of the Replacement Hospital in the event (i) a Certificate of Need cannot be reasonably attained or (ii) at any time prior to completion of the Replacement Hospital, there is a material, adverse change in government or third-party payor reimbursement such that, in Lessee's sole

judgment, the Replacement Hospital cannot be operated in an economically viable manner.

(b) During the first thirty-six (36) months of the Initial Term, make Four Million Dollars ($4,000,000) in capital expenditures as Lessee's Board of Directors deems appropriate and necessary for general facility improvements at the Hospital, which shall include, but not be limited to, expenditures for additional or upgraded equipment acquisitions through lease or purchase, installation of information system improvements at the Hospital, and to maintain the Hospital's existing accreditations, licenses and permits and respond to technological advances to enhance the quality of care the Hospital provides. Expenditures made by Lessee to satisfy the requirements of this Subsection 5.2(b) shall be reflected in annual reports submitted by Lessee to City. If for any reason, Lessee does not expend a total of Four Million Dollars ($4,000,000) in accordance with this Subsection 5.2(b), Lessee shall place in a mutually agreeable escrow account an amount equal to the difference between Four Million Dollars ($4,000,000) and what amount was expended for such improvements to be used for future capital expenditures at the Hospital by Lessee or any future owner or operator of the Hospital. Provided, however, Lessee shall receive credit towards its obligation as provided in this Section 5.2(b) for any amounts credited by Lessee, in its sole discretion, in calculating Net Working Capital, for fixed assets purchased by Hospital within sixty (60) days of the Commencement Date. Provided further, however, Lessee shall also receive credit towards its obligation as provided in this Section 5.2(b) in the amount of $631,460.00 in connection with the Hospital's acquisition of the General Electric CT Scanner by contract dated January 13, 2000, which contract is hereby assumed by Lessee. Notwithstanding anything in this Section 5.2(b) to the contrary, in the event Lessee or St. Mary's, within the first thirty-six (36) months of the Initial Term, notifies the City in writing of its commitment to build a Replacement Hospital, Lessee is relieved and shall not be required to make any further capital expenditure under this Section 5.2(b).

(c) During the Initial Term of this Agreement, upon demonstrable need and as permitted by law, commit resources to expanding clinical services at the Hospital and to a recruitment and incentive plan to be used to attract physicians, as identified in the Hospital's medical staff development plan, to the Hospital to serve the health needs of the community and assist in the identification of opportunities for additional or enhanced clinical services at the Hospital.

(d) During the Lease Term, pay all costs and expenses of the operation and maintenance of the Leased Premises when and as the same shall be due and payable.

(e) During the Lease Term, pay, as part of the cost of operating and maintaining the Leased Premises, all taxes and assessments, if any, that may be levied against the same; provided, however, that the City shall, with all dispatch, cooperate with

Lessee in any manner reasonably requested by Lessee to assist Lessee in its efforts to take steps that may reasonably be required at any time and from time to time for the purpose of establishing and continuing to maintain, if practicable, the exemption of the Leased Premises in their entirety from any and all assessment and taxation.

(f) During the Initial Lease Term, Lessee shall operate a Health Care Facility as a part of the Hospital.

In the event the Lessee fails to make any of the payments required in this Section 5.2, the item or installment so in default shall continue as an obligation of the Lessee until the amount in default shall have been fully paid and such payment obligation shall survive the expiration of the Lease Term or the termination of this Agreement by City for a default by Lessee.

Section 5.3. Obligations of Lessee Hereunder Unconditional. Unless otherwise provided in this Agreement, the obligations of the Lessee to make the payments required in this Article V and to perform and observe the other agreements on its part contained in this Article V shall not be subject to diminution by set-off, counterclaim, abatement or otherwise and the Lessee (i) will not suspend or discontinue or permit the suspension or discontinuance of any such payments, (ii) will perform and observe all its other agreements contained in this Agreement, and (iii) will not terminate the Lease Term for any cause except those specifically permitted herein. Without limiting the generality of the foregoing, any acts or circumstances that may constitute failure of or damage to the Leased Premises, commercial frustration of purpose, any change in the tax or other laws or administrative rulings of or administrative actions by the United States of America or the State of Tennessee, or any failure of the City to perform and observe any agreement, whether express or implied, duty, liability or obligation arising out of or connected with this Agreement, provided such failure does not unreasonably interfere with Lessee's use and possession of the Leased Premises in the manner hereby contemplated, will not be cause for termination hereof by Lessee. To the extent permitted by law, the Lessee may at its own cost and expense and in its own name or that of the City prosecute or defend any action or proceeding or take any other action involving third persons that the Lessee deems reasonably necessary to secure or protect its right of possession, occupancy, and use of the Lease Premises hereunder; and, in such event, the City hereby agrees to cooperate fully with the Lessee and to take all action necessary to effect the substitution of the Lessee for or the joinder of the Lessee with the City in any such action or proceeding if the Lessee shall so request.

Article VI
Warranties and Covenants

Section 6.1. Warranties and Covenants of City. The City warrants, covenants and agrees that:

(a) If the Lessee shall keep and perform the covenants in this Agreement on its part to be kept and performed, the Lessee shall peaceably and quietly hold, occupy and enjoy the Leased Premises during the term of this Agreement or any extension or

renewal thereof, without any hindrance or molestation by the City or any person or persons lawfully claiming under it.

(b) Except as herein otherwise expressly provided, as of the Commencement Date, full administrative and operational control of the Leased Premises, including, without limitation, the Hospital, is be vested in the Lessee and not subject to the oversight, control, or review of the City or any other entity related to the City or described in the City Charter.

(c) Except as herein otherwise expressly provided, the City shall not be required to construct or install any facilities, improvements or equipment in or on the Leased Premises.

(d) Except as herein otherwise expressly provided, the Lessee shall have the right from time to time at its sole cost and expense to make repairs, restorations, replacements, additions, alterations and changes, whether structural or nonstructural, in or to the Leased Premises.

(e) It is not aware of any noncompliance with any environmental laws concerning the Leased Premises, including, without limitation, the presence or absence of asbestos, petroleum products, hazardous wastes, illegal substances, toxic substances, and all other pollutants and contaminants, and agrees to be responsible for, save, indemnify, and hold Lessee harmless from any and all investigations, litigation, claims, disputes, damages, cost of clean-up, and/or corrective actions and liabilities, including, but not limited to, attorneys' fees and court costs, of any nature whatsoever required or arising out of the City's or Hospital's noncompliance with any environmental laws involving the Leased Premises that existed before or at the Commencement Date; provided, however, the City shall not be responsible for the cost of asbestos clean-up, removal or abatement resulting from renovation of the Leased Premises after the date hereof.

(f) It shall be responsible for any noncompliance occurring before and existing at the Commencement Date with regard to Medicare, Medicaid, and/or TennCare laws, rules, regulations, and/or policies or those applicable to programs of any other third-party payors governing reimbursement for services rendered to participants in such programs that could result in the Hospital's being subjected to fines or penalties or being forced to reimburse any such payors for monies paid to the Hospital for services. City agrees that, if the Hospital is found to have violated any of said laws, rules, regulations and/or policies, it shall indemnify Lessee as set forth under Section 10.2 for reimbursement relating to, concerning, or arising from such violations, including, but not being limited to, fines, interest, and penalties sought to be imposed by such payors for the Hospital's violations that occurred before or existed at the Commencement Date. In the event any such payor offsets against payments due Lessee such amounts owed by the City or Hospital to such payor, the City agrees to reimburse Lessee for such offsets. The foregoing notwithstanding,

the parties agree and stipulate that the Net Working Capital transferred to the Lessee at the Commencement Date, as provided in Section 3.4, above, includes an amount for reserves payable to and receivable from third-party payors for cost report settlements ("Reserves"); and, with regard to the settlement of such third-party payor cost reports, the parties agree as follows:

(i) if such settlements collectively result in total receipts by Lessee from such payors in excess of $100,000 over the Reserves ("Excess Receipts"), Lessee will pay the Excess Receipts to the City; or,

(ii) if such settlements collectively result in total payments by Lessee to such payors in excess of $100,000 over the Reserves ("Excess Payments"), the City shall reimburse Lessee in the amount of such Excess Payments.

Lessee will provide documentation to the City supporting the payment of Excess Receipts or the deduction of Excess Payments at the time any such payment or deduction is made or taken. The City may contest such payment or deduction or the amount thereof by giving Lessee notice thereof with ten (10) business days of the receipt of such documentation. Upon receipt of such notice, representatives of the City and Lessee will meet within five (5) business days and use their reasonable best efforts to resolve the matter.

(g) It shall apply the Prepaid Basic Rent as set out in Section 5.1(a) to the satisfaction of any and all liabilities, other than Current Obligations and Hospital Equipment Leases, relating to, arising from or connected with the Leased Premises, including, without limitation, the Hospital Notes and Hospital Bonds, incurred before or existing at the Commencement Date. Upon written request by Lessee, the City shall provide Lessee with written verification of the payment of such liabilities.

(h) It shall, for itself and Lessee, resist and defend any administrative or judicial challenge to the legality of this Agreement or the legal authority of City to enter into the same. City further agrees and warrants that, if any such challenge should be successful and this Agreement is declared to be invalid, it will repay to Lessee any and all payments of Prepaid Basic Rent, rent paid during any Renewal Term, and additional consideration paid by Lessee in accordance with Section 5.2, above.

(i) In the event Lessee builds a Replacement Hospital pursuant to the terms of this Agreement, the City agrees that it will contribute up to Seven Hundred Fifty Thousand Dollars ($750,000) towards the project for land acquisition and site preparation and the extension and construction of utilities, access, and roads.

(j) During the Lease Term and for a period of ten (10) years following the completion of the Replacement Hospital, the City shall not, directly or indirectly, develop, finance, construct, operate, or provide support to any Health Care Facility, nursing home, medical office building, or home health agency in the City or County which

provides services in competition with the Hospital, nor shall the City permit any of its subordinate organizations or entities to do so.

Section 6.2. Warranties and Covenants of Lessee. The Lessee warrants, covenants and agrees that:

(a) It shall use and occupy the Leased Premises and, during the Initial Term of this Agreement, shall faithfully administer, operate and maintain a Health Care Facility thereon, which, to the extent facilities and capabilities permit, shall be open at all times and without discrimination as to race, creed, color, sex, national origin, or disability to residents of the City and County and members of the general public, in each case as determined in accordance with appropriate and reasonable admission policies of its sole member.

(b) It shall administer, operate and maintain the Leased Premises in accordance with the terms of this Agreement; and, in the discharge of its obligations hereunder, shall conform to and abide by all present and future applicable laws, ordinances, rules, regulations, requirements, and orders of all governmental authorities or agencies having jurisdiction over the Leased Premises or the operations of the Lessee; provided, however, that nothing herein contained shall require the Lessee to comply with, observe, and conform to any such law, ordinance, rule, regulation, requirement or order so long as the validity thereof or the applicability thereof shall be contested in good faith; and, provided further, however, that the terms and conditions of this Agreement shall not be altered by any ordinance, resolution or other proceedings of the Governing Body without the prior written consent of the Lessee. Except as herein otherwise expressly provided, all costs of administration, operation and maintenance of the Leased Premises shall be the exclusive obligation of the Lessee and shall be discharged by the Lessee at its sole expense.

(c) It shall use and occupy the Leased Premises in a careful, safe, and proper manner and for lawful purposes only and shall commit no waste and shall suffer no waste to be committed thereon.

(d) It shall, at its expense and at all times, keep the Leased Premises insured against loss or damage by fire or other casualty by a policy or policies of full extended coverage insurance in a company or companies of good standing and qualified to write such insurance in the State of Tennessee or a suitable program of self-insurance. Such insurance or self-insurance program shall be for an amount not less than the full insurable value of the Leased Premises, including completed improvements and additions thereto or any separable portion thereof as determined by and upon certification by the architect. Each such policy shall provide that the loss, if any, shall be payable to the City or a payee designated by the City. If, at any time during the Lease Term, the Leased Premises are destroyed or damaged and such destruction or damage was covered by or attributable to a casualty covered by such insurance or self-insurance program, as required by this Section

6.2(f), City shall use its reasonable best efforts, exercised promptly and diligently, to repair such damage and reconstruct and restore the Leased Premises as soon as reasonably possible and as near to their former condition as practicable at City's expense, using the proceeds of such insurance or self-insurance program exclusively for such purposes, and this Agreement shall continue in full force and effect. City shall not be required to expend any sums in excess of the proceeds of such insurance or self-insurance program for the repair, reconstruction, or restoration of the Leased Premises. If it is reasonably practicable to do so, Lessee shall continue the operation of the Hospital on the Leased Premises during the period the damage, destruction, repair, reconstruction, or restoration continues, and the rent payable under Section 5.1(b) shall be abated in such proportion as the area damaged or destroyed bears to the total area of the facilities and improvements subject to this Agreement; provided, however, if, during such period, it is not reasonably practicable to operate the Hospital on the Leased Premises, the Lessee may cease operations of the Hospital, and the rent payable under Sections 5.1(b) and 5.2(b) shall be fully abated until the repairs are made and the reconstruction and restoration completed and, at Lessee's sole option, the Lease Term shall be extended for a like period.

(e) It shall further, at its expense and at all times, maintain general liability insurance or one or more suitable self-insurance programs to cover such risks and in such amounts as, in its judgment, are adequate to protect it and its properties and operations.

(f) It shall further, at its expense and at all times, procure and maintain a policy or policies of professional liability insurance in a company or companies of good standing qualified to write such insurance in the State of Tennessee or a suitable program of self-insurance in an amount not less than that maintained by its sole member for hospital facilities operated by it or its affiliates.

(g) Each policy or program of self-insurance provided for in subsections (d), (e) and (f) of this Section 6.2 shall, during the Lease Term, name or carry an endorsement including City as an additional insured and shall be cancelable only upon at least ten (10) days' written notice to the City. A duplicate original of each such policy or a certificate or certificates in evidence thereof shall be delivered to and held by the City.

(h) It shall, at its own cost and expense, keep the Leased Premises in good repair and order, reasonable wear and tear excepted, and in as reasonably safe condition as its operations will permit and make all necessary repairs thereto, interior and exterior, structural and nonstructural, ordinary as well as extraordinary, and foreseen as well as unforeseen, and all necessary replacements or renewals, subject in all respects to the receipt by the Lessee of all necessary governmental permits and approvals therefor; provided, however, that except as otherwise required by Sections 4.4, 5.2(e), and 6.2(a) of this Agreement, nothing herein contained shall be construed

to prevent the Lessee from discontinuing the use and operation of any non-essential part of the Leased Premises, including disposal of Leased Equipment, if in its sole judgment it is no longer cost effective to use and operate such part.

(i) It shall not sublease the Leased Premises or any part thereof or assign this Agreement without having obtained in each case the prior consent of the Governing Body of the City to be evidenced by its duly adopted and effective resolution, and the Lessee further shall not permit a transfer, by operation of law or any process or court proceedings, of the Lessee's interest in the Leased Premises acquired hereunder, except that, subject to the provisions of Section 12.2, the prior consent of such Governing Body shall not be required with respect to (i) an assignment to any other non-profit corporation, the sole member of which is Lessee's sole member (or its successor), or which is affiliated with or controlled, directly or indirectly, by Lessee's sole member (or its successor), (ii) sublease for patient or employee convenience activities such as, but not limited to, gift shops, snack shops, barber or beauty shops, doctors' or dentists' accommodations, flower shops, counseling services, laundry services, pharmacy, and living accommodations for persons providing services within the Leased Premises, or for services related to the operation of the Leased Premises as a Health Care Facility such as, but not limited to, physician's offices, pathology, x-ray, physical medicine, anesthesiology, electro-cardiology and emergency room operations, or (iii) any leases, subleases, assignments, or uses extant on the Commencement Date; provided, however, no such transfer, assignment or sublease shall conflict with the covenants of the Lessee under this Agreement or relieve the Lessee of its obligations hereunder for payment of rent or from any other of the conditions, obligations, agreements and covenants of this Agreement or with respect to any portion of the Leased Premises so transferred, assigned or subleased; and, provided further, however, that in each case the transferee, assignee or sublessee shall have sufficient financial responsibility and technical competence to conduct in an adequate manner the functions contemplated by the sublease; and provided further, however, that Lessee shall require any sublessee described in (ii) above to obtain and maintain insurance reasonably adequate to insure against risks arising from such sublessee's operations on the Leased Premises.

(j) Recognizing the need to safeguard the City's interest in the Leased Premises and in the operation of the Health Care Facility thereon, the Lessee shall immediately notify the City of any and all legal process or other material notification concerning any judicial proceedings, including bankruptcy, or any proceeding of a quasi-judicial nature before any administrative board, commission, or other body which, in the reasonable exercise of the Lessee's best judgment, would jeopardize such interest of the City. Lessee shall also notify the City of notification of any material noncompliance with regard to Medicare, Medicaid and/or TennCare laws, to the extent such alleged noncompliance could cause the total cessation of Lessee's operation of the Leased Premises. Lessee shall be responsible for any and all

liability connected with acts or events of noncompliance with regard to Medicare, Medicaid and/or TennCare laws that occur on or after the Commencement Date.

(k) It shall pay all charges for utility services furnished to the Leased Premises.

(l) It shall allow the Authorized City Representative or such person's designee free access to the Leased Premises at all reasonable times for the purpose of examining the same.

(m) It shall at all times conduct the operation of the Hospital (other than facilities not subject to accreditation) in a manner acceptable to the Joint Commission on Accreditation of Health Care Organizations or its successor, provided, however, that it need not comply with this subsection (o) if and to the extent that the Lessee's governing body shall have determined in good faith, evidenced by a resolution of the governing body, that such compliance is not in its best interests and that lack of such compliance would not materially impair the Lessee's ability to comply with the other requirements applicable to Lessee hereunder.

(n) During the Lease Term, the Lessee's organizational documents shall provide that its Board of Directors will consist of nine (9) members, including the Hospital's Chief of Staff and Administrator and two persons designated by Lessee's sole member, with the remaining members to be representative of the community and appointed by the Lessee's sole member. Lessee's organizational documents shall provide that its Board of Directors will meet regularly and have the authority to grant medical staff privileges to physicians, assist in developing policies governing the operation of the Hospital, and make recommendations to Lessee's sole member regarding services to be offered at the Hospital, strategic and facility planning budgets, equipment and capital needs of the Hospital, and the selection and retention of the Hospital's Administrator.

(o) Subject to applicable law, the Lessee accepts assignment of only those existing contracts of the Hospital with medical service providers and equipment suppliers as are set out on Exhibit F, hereto, and Lessee agrees to maintain the contracts set out on Exhibit F for their current terms absent default or breach thereof by the parties providing services and supplies. Any and all such contracts that are not set out on Exhibit F shall be and remain the responsibility of the City.

(p) Upon the Commencement Date, the Lessee agrees to offer employment to the Hospital's then-current employees at wages and benefits comparable to those presently enjoyed by such employees. Both parties agree that long-term staffing decisions will be determined by Lessee. The Lessee agrees to honor prior service credit under the Hospital's current welfare benefit plans for the purpose of satisfying pre-existing conditions thereunder and for the purpose of determining eligibility and vesting in Lessee's retirement benefit plans.

(q) During the Lease Term, the Lessee agrees to provide care to indigent patients in accordance with the policies and practices of its sole member, which indigent care shall, during the Initial Term, be at least at the same level of funding as provided by the Hospital for the fiscal year last preceding the Commencement Date.

(r) Recognizing that another location may ultimately be more advantageous and conditions not now known or foreseen may ultimately indicate another location is more appropriate, Lessee shall construct the Replacement Hospital, if one is built within the Lease Term, within the corporate limits of the City or an annexable area of the City. If, in the opinion of Lessee's Governing Body, construction of the Replacement Hospital within the corporate limits of the City is prohibitive or not feasible, Lessee may request relief from this requirement from the City's Governing Body. If, within sixty (60) days of written notice of such request given pursuant to Article XI of this Agreement, the Governing Body of the City has not by resolution denied such request, then it shall be conclusively presumed that this Section 6.2(r) shall have no application; provided, however, in no event shall the Replacement Hospital, if one is built within the Lease Term, be built outside the boundaries of the County.

Section 6.3 Warranties and Covenants of St. Mary's. St. Mary's warrants, covenants and agrees that:

(a) It guarantees the full and prompt performance by Lessee of all of its obligations under this Agreement.

(b) It will monitor Lessee's compliance with Section 5.2(a), above, and, subject to the approvals of its Governing Bodies and the terms and conditions set out in Section 5.2(a), above, consent to the construction of the Replacement Hospital.

(c) It will monitor Lessee's compliance with the Section 6.2, above, and require corrective action as necessary and appropriate.

Article VII
Condemnation

In the event of a taking of all or any portion of the Leased Premises by condemnation, eminent domain or other process of any governmental authority other than the City, the Lessee shall waive any rights which it may have to any portion of the proceeds of the award for such taking, except to the extent hereinafter provided. Such proceeds shall be deposited in such lawful manner as the City shall direct and the same, at the direction of the City, shall be expended, to the extent possible, for the replacement of any portion of the Leased Premises so taken. The City, upon being notified of any action or proceeding to take all or any portion of the Leased Premises, shall immediately notify the Lessee of the pendency of such action or proceeding. If, after such taking of any portion of the Leased Premises, the remaining portion is determined by the Lessee to be

insufficient for further operation as a Health Care Facility, this Agreement shall terminate without penalty to either party hereto as of the effective date of such taking, and City shall use said proceeds to reimburse Lessee for any and all improvements made to the Leased Premises that have not been credited to Lessee as rental payments under Section 5.1 (a) and (b) and for all funds expended pursuant to Sections 5.2 (a), (b), (c), (d), and (e).

If a partial taking of the Leased Premises by condemnation, eminent domain or other process shall occur and if the Agreement does not terminate and is not otherwise terminated as provided herein, the Lessee shall be allowed a proportionate reduction in the rental herein provided to be paid to the City corresponding to the time during which and the extent to which the Lessee shall be deprived of the use and occupancy of the Leased Premises or any portion thereof.

A sale or transfer of all or any portion of the Leased Premises by City to any authority having the power of eminent domain, either under threat of condemnation or while condemnation proceedings are pending, shall be deemed a taking under the power of eminent domain for all purposes of this Article VII.

The City hereby warrants and covenants that it will take no action to condemn or take by way of eminent domain the Lessee's leasehold interest in the Leased Premises granted pursuant to this Agreement.

Article VIII
Defaults and Remedies

Section 8.1. Events of Default by Lessee. The following shall be "events of default" by Lessee under this Agreement and the term "event of default" shall mean, whenever used in this Agreement with respect to Lessee, any one or more of the following events:

(a) The Lessee shall default in the payment of any rentals hereunder and such default shall have continued for a period of ten (10) days after the same shall become payable or the Lessee shall make default in the payment of any other monies which may become payable hereunder and such default shall have continued for a period of thirty (30) days;

(b) The Lessee shall have admitted in writing it is insolvent or shall have filed a petition asserting it is a bankrupt or shall have made an assignment for the benefit of its creditors;

(c) Possession of all or substantially all of the Lessee's assets shall be taken by a receiver or trustee;

(d) The Lessee shall sublease the Leased Premises or any part thereof, except as otherwise herein permitted, or the interest of the Lessee under this Agreement shall be sold, assigned, or transferred under legal process or otherwise to any other

person, firm or corporation without the prior written consent of the Governing Body as herein provided;

(e) The Lessee shall have materially failed to perform or observe any other covenant required to be performed or observed by the Lessee under the terms of this Agreement, including but not limited to the covenant to operate a Health Care Facility on the Lease Land during the Initial Term, and the Lessee shall, within thirty (30) days after written notice thereof approved by resolution of the Governing Body and given pursuant to Article XI, below, fail to commence appropriate action in good faith to cure such failure and thereafter to prosecute the same to completion with due diligence; or,

(f) The Lessee shall have vacated the Leased Premises.

Section 8.2. Remedies Upon Event of Default by Lessee.

(a) Monetary Default. Whenever any Event of Default referred to in Section 8.1(a) shall have happened and shall not have been cured within fifteen (15) days after written demand is given by the City to the Lessee, in addition to any other required notice, any one or more of the following remedial steps may be taken by the City:

(1) City may take whatever action in law or equity may appear necessary or desirable to collect the rent then due and thereafter to become due or to enforce performance and observance of any obligation, agreement, or covenant of the Lessee under this Agreement.

(2) City may re-enter and take possession of the Leased Premises without terminating this Agreement and sublease the Leased Premises for the account of the Lessee, holding the Lessee liable for the amount by which the rent and other amounts payable by such sublessee in such subleasing are less than the rents and other amounts payable to the Lessee hereunder.

(3) City may terminate the Agreement, exclude the Lessee from possession of the Leased Premises, and use its best efforts to lease the Leased Premises to another, but holding the Lessee liable for all rent and other payments due up to the effective date of such leasing.

(b) Nonmonetary Default. Whenever any Event of Default referred to in Section 8.1 (b) through (e) shall have occurred and shall continue for sixty (60) days following written notice thereof from the City to the Lessee, given in accordance with Article XI, the City may, at its sole option, do or cause to be done such act or thing constituting such Event of Default on behalf of the Lessee and, upon written notification to the Lessee of the cost thereof, the Lessee shall pay promptly to the City the amount of such cost.

(c) Default Upon Vacating Premises or Failing to Operate a Health Care Facility During Initial Term. Whenever, during the Initial Term of this Agreement, an Event of Default referred to in Section 8.1 (f) or upon Lessee's failure to operate a Health Care Facility following the procedures set out in Section 8.1(e) shall have occurred and shall have continued for fifteen (15) days following written notice thereof from the City to the Lessee, given in accordance with Article XI, the Lessee shall pay to the City, as liquidated damages and in lieu of all of damages of any kind whatsoever, the sum of Two Million Dollars ($2,000,000).

Section 8.3. Events of and Remedies Upon Default by City. It shall be an Event of Default by the City if it shall neglect or fail to perform or observe any warranties, covenants, representations, provisions, or conditions made by or required to be performed by City under the terms of this Agreement, including, without limitation, the City's failure to indemnify the Lessee as provided herein, and City shall within thirty (30) days, after written notice thereof by Lessee, fail to commence appropriate action in good faith to cure such failure and thereafter prosecute the same to completion with due diligence. The City shall be responsible to Lessee for any and all damages sustained by Lessee as a result of an Event of Default by the City, and Lessee shall have the right, in addition to all other remedies provided in this Agreement or by law, to injunctive relief; provided, further, Lessee shall have the right to cure any such Event of Default at the City's expense, including in such expense all costs and legal fees incurred to cure such Event of Default, and City shall pay promptly to the Lessee the amount of such expenditure by Lessee to cure such Event of Default by the City.

Section 8.4. Provisions Applicable to Both Parties.

(a) Remedies Cumulative. No remedy conferred upon or reserved to either party by this Agreement is intended to be exclusive of any other available remedy or remedies, but each and every such remedy shall be cumulative and shall be in addition to every other remedy given under this Agreement or now or hereafter existing at law or in equity or by statute. No delay or omission to exercise any right or power accruing upon any default shall impair any such right or power or shall be construed to be a waiver thereof, but any such right and power may be exercised from time to time and as often as may be deemed expedient. Each party shall give the other party notice in accordance with Article XI, and a reasonable opportunity to cure prior to exercising any remedy reserved to such party in this Agreement.

(b) Attorney's Fees and Litigation Expenses. In the event a party should default under any of the provisions of this Agreement and the other party should employ attorneys or incur other expenses for the enforcement or performance or observance of any obligation or agreement on the part of either party contained in this Agreement, the defaulting party agrees that it will on demand therefor reimburse the other for the reasonable fees of such attorneys and such other expenses so incurred.

(c) Waiver and Breach. In the event any agreement contained in this Agreement should be breached by either party and thereafter waived by the other party, such waiver shall be limited to the particular breach so waived and shall not be deemed to waive any other breach hereunder.

Article IX
Termination

Section 9.1. Termination by Lessee. Provided no event of default by Lessee hereunder has occurred and is continuing, the Lessee may, by notice to the City of its decision to do so, terminate this Agreement, subject to the conditions set forth below, for any of the following reasons:

(a) In the event legislation is enacted or by order of a duly constituted court or governmental agency, procedures may be required to be performed on the Leased Premises, which are contrary to the philosophy of the Sisters of Mercy, morally or otherwise, the Lessee, upon three (3) years' prior written notice, may terminate this Agreement, and, during the period between the giving of such notice and the termination of the Agreement, the Lessee shall not be obligated to perform such procedures and the failure on the part of the Lessee to perform such procedures shall not constitute a breach of this Agreement; provided, however, that City may terminate this Agreement upon ninety (90) days' written notice to Lessee of its intent to do so if City would be in violation, in any material respect, of any statute or law as a result of Lessee's failure to perform such procedures; provided further, however, said ninety (90) day period shall be extended if, either before the giving of such notice by City or within ninety (90) days thereafter, Lessee has, in good faith, commenced an action in a court of competent jurisdiction to challenge the validity or applicability of such law, statute or order to Lessee's operation of the Hospital, and such extension shall continue until Lessee's action has been finally adjudicated and no appeal has been taken or the time for taking an appeal has expired; provided, further, however, Lessee shall indemnify and hold City harmless from and against any and all liabilities incurred or suffered by City arising from City's inability to terminate this Agreement during the period Lessee is so challenging such law, statute, or order. During such three-year period, the City and the Lessee shall jointly and diligently undertake and use their respective best efforts to find a successor or make other arrangements to take over the operation of the Leased Premises so as to permit the Lessee to terminate this Agreement at the earliest possible date within such three-year period.

(b) The Lessee may, at its option, terminate this Agreement if the Leased Premises are destroyed or materially damaged and not repaired, reconstructed or replaced or if title to or the use of the Leased Premises or any material part thereof is taken under exercise of the power of condemnation, eminent domain or other process and not replaced or restored.

(c) The Lessee may, at its option, terminate this Agreement upon its purchase of the Leased Premises pursuant to the exclusive option set out in Section 3.2, above. Such termination shall be effective as of the closing of Lessee's purchase of the Leased Premises.

Section 9.2. Termination by City. The City may only terminate this Agreement upon the occurrence and continuation of an event of default under Section 8.1, above.

Section 9.3. Reversion of Leased Premises to City. Upon termination of this Agreement, by either the City or the Lessee, for any reason, other than the reason set out in Section 9.1 (c), above, the Leased Premises, including all replacement and additional furnishings and equipment installed or placed in or on the Leased Premises before termination, shall revert to the City.

Article X
Release and Indemnity

Section 10.1. Indemnification of City. Lessee releases the City from, agrees that the City shall not be liable for, and agrees to hold the City, its officers, employees and agents and the members of the Governing Body of the City, harmless against, any and all losses, liabilities, damages, costs (including court costs and cost of appeal) and expenses (including reasonable attorneys' and experts' fees) that the City incurs as a result of or with respect to (i) any inaccuracy in any of the representations made by the Lessee in this Agreement; (ii) any material breach or non-fulfillment of any covenants or warranties made by the Lessee in this Agreement; and (iii) any loss or damage to property or any loss for injury to or death of any person or any other loss or damage that may be occasioned by any cause whatsoever pertaining to the Leased Premises or the use thereof provided that the sole cause or the substantial contributing cause thereof occurs on or after the Commencement Date; and provided further, that this indemnification shall be effective only to the extent of any loss that may be sustained by the City or its officers, employees or agents or the members of such Governing Body in excess of the proceeds from any insurance policy maintained by the Lessee pursuant to this Agreement and received by the City with respect to the loss sustained. The Lessee further agrees to indemnify and hold harmless the City and its officers, employees and agents and the members of such Governing Body against and from any and all cost, liability, expenses, including, without limitation, reasonable attorneys' fees, and claims arising from the acquisition, construction, installation or improvement of any facilities or other improvements in and about the Leased Premises, or arising from any act or negligence of or failure to act by the Lessee or any of its agents, contractors, servants, employees, or licensees, or arising from any accident, injury or damage whatsoever caused to any person, firm or corporation occurring during the Lease Term in or about the Leased Premises, and from and against all cost, liability and expenses incurred in or in connection with any such claim.

Section 10.2. Indemnification of Lessee. The City releases the Lessee from, agrees that the Lessee shall not be liable for, and agrees to hold the Lessee, its officers, employees, agents, and the members of its Board of Directors, harmless from any and all losses, liabilities, damages, costs (including court costs and cost of appeal) and expenses (including reasonable attorneys' and experts'

fees) that the Lessee incurs as a result of or with respect to (i) any inaccuracy in any of the representations made by the City in this Agreement; (ii) any material breach or non-fulfillment of any covenants or warranties made by the City in this Agreement; and (iii) any and all litigation, claims or disputes, whether or not pending at the Commencement Date, asserted or unasserted, known or unknown, including, but not being limited to, any professional liability, other tort, or contract claims that are related to, concern, or arise out of any incident, occurrence, act, or omission occurring before the Commencement Date of this Agreement. In the event the Lessee is made a party to any proceeding to which it is entitled to indemnification under this Section 10.2, Lessee shall have the right to appear in such proceeding for itself and the City and shall, at the City's expense, obtain appropriate representation for the proceeding and otherwise direct the defense of any such litigation, claims, or disputes.

Article XI
Notices

Any notice or notification specified in this Agreement to be given to the Lessee, St. Mary's, or the City shall be deemed effective upon the earlier of actual delivery or three (3) days following the date such notice shall have been mailed by United States certified mail, postage prepaid, addressed to the Lessee or to the City, respectively, as follows:

City: Mayor of the City of LaFollette
205 South Tennessee Avenue
LaFollette, TN 37766

Lessee: Mr. Richard C. Williams
Vice-Chairman and President
LaFollette Medical Center, Inc.
900 E. Oak Hill
Knoxville, TN 37917-4556

St. Mary's: Mr. Richard C. Williams
President and CEO
St. Mary's Health System, Inc.
900 E. Oak Hill
Knoxville, TN 37917-4556

Either the City or the Lessee may, however, from time to time by notice in writing to the other party establish an addressee or an address differing from the foregoing for the purpose of giving notice or notification under this Agreement. Any notice or notification specified in this Agreement to be given to the Lessee shall also contemporaneously be given to St. Mary's.

Article XII
Miscellaneous Provisions

Section 12.1 Arbitration. Except as specifically modified by this Section 12.1, any controversy or claim arising out of or relating to this Agreement or its breach, including, without limitation, any claim that this Agreement or any of its parts is invalid, illegal or otherwise voidable or void, shall be submitted to arbitration before and in accordance with the commercial arbitration rules of the American Arbitration Association ("AAA"). The provisions of this Section 12.1 will be construed as independent of any other covenant or provision of this Agreement; provided that, if a court of a competent jurisdiction determines that these provisions are unlawful in any way, the court may modify or interpret them to the minimum extent necessary to have them comply with the law. Judgment upon an arbitration award may be entered in any court located in Knoxville, Tennessee, having competent jurisdiction and will be binding, final and non-appealable. The parties hereby waive, to the fullest extent permitted by law, any right or claim for any punitive or exemplary damages against the other and agree that, in the event of a dispute, each shall be limited to the recovery of actual damages sustained. This arbitration provision is deemed to be self-executing and will remain in full force and effect after expiration or termination of this Agreement. In the event either party fails to appear at any properly noticed arbitration proceeding, an award may be entered against such party by default or otherwise notwithstanding that failure to appear. Arbitration will take place in Knoxville, Tennessee, and, all controversies shall be governed by and construed under the laws of the state of Tennessee. The obligation to arbitrate will not be binding upon claims relating to the violation or alleged violation of the covenant not to compete set out in Section 6.1(j), above; claims relating to the exclusive purchase option set out in Section 3.2, above; or, requests by either party for temporary restraining orders, preliminary injunctions or other equitable procedures in a court of competent jurisdiction to obtain interim relief when deemed necessary by such court to preserve the *status quo* or prevent irreparable harm or injury pending resolution by arbitration of the actual dispute between the parties.

Section 12.2. Acceptance of Federal Funding. The City and the Lessee shall have full power and authority, jointly and severally, to accept federal funds for the improvement of the Leased Premises.

Section 12.3. Severability. In the event any provision of this Agreement shall be held invalid or unenforceable by any court of competent jurisdiction, such holding shall not invalidate or render unenforceable any other provision hereof or such otherwise invalid provision under circumstances other than those under which it was determined to be invalid, except to the extent that such other provision is wholly dependent for its operation upon the part declared to be invalid, and to that end the provisions hereof are agreed and declared to be severable.

Section 12.4. Immunity of Officers and Directors, Etc. No recourse shall be had on any obligation, covenant or agreement in this Agreement against any past, present or future incorporator, official, officer, director, or employee of the City or the Lessee, as such, either directly or indirectly, under any rule of law or equity, statute or constitution, or by the enforcement of any assessment or penalty or otherwise, and all such liability of any such incorporators, officials, officers, directors,

or employees as such, is hereby expressly waived and released as a condition of and consideration for the execution and delivery of this Agreement.

Section 12.5. Amendments and Modifications. This Agreement shall not be amended or modified except by a written instrument signed by the duly authorized representatives of each of the parties hereto.

Section 12.6. Captions. The titles of articles, sections, subsections, or paragraphs herein are solely for the convenience of the parties and shall not be used to explain, limit, expand, modify, simplify, or aid in the interpretation of the provisions of this Agreement.

Section 12.7. Assignments. Except as herein otherwise expressly provided, no party hereto may assign or otherwise transfer its rights or obligations hereunder without the prior written consent of the other parties hereto.

Section 12.8. Entire Agreement. This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and the transactions hereby contemplated. Any prior understandings, proposals, or representations of any kind shall not be binding upon either party except to the extent incorporated in this Agreement.

Section 12.9. Governing Law. This Agreement shall be governed by and construed in accordance with the Constitution, laws and regulations of the State of Tennessee without regard to provisions with respect to conflicts or choices of law.

Section 12.10. Execution in Counterparts. This Agreement may be executed in several counterparts, each of which shall be an original and all of which shall constitute but one and the same instrument.

[The balance of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their respective duly authorized officers as of the day and date first above written.

CITY:

THE CITY OF LaFOLLETTE, TENNESSEE

By: _____
Clifford Jennings, Mayor

LESSEE:

LaFOLLETTE MEDICAL CENTER, INC.

By: _____
Richard C. Williams, Vice-Chairman and President

ST. MARY'S:

ST. MARY'S HEALTH SYSTEM, INC.

By: _____
Richard C. Williams, President and CEO

ACKNOWLEDGMENTS

STATE OF TENNESSEE }
COUNTY OF CAMPBELL }

Before me, a Notary Public in the State and County aforesaid, personally appeared Clifford Jennings, with whom I am personally acquainted, or proved to me on the basis of satisfactory evidence, and who, upon oath, acknowledged himself to be the incumbent Mayor of the City of LaFollette, Tennessee, and that he as such incumbent Mayor, being authorized so to do, executed the foregoing instrument for the purposes therein contained, by signing his name as the incumbent Mayor of the City of LaFollette, Tennessee.

WITNESS my hand and official seal at office this 27th day of April, 2000.

Notary Public

My commission expires:

May 6, 2001

STATE OF TENNESSEE }
COUNTY OF CAMPBELL }

Personally appeared before me, a Notary Public in the State and County aforesaid, Richard C. Williams, with whom I am personally acquainted, or proved to me on the basis of satisfactory evidence, and who, under oath, acknowledged himself to be the Vice-Chairman of the Board of Directors and President of LaFollette Medical Center, Inc., the within-named bargainor, a corporation, and that he as such Vice-Chairman of the Board of Directors and President, being authorized so to do, executed the foregoing instrument for the purposes therein contained, by signing the name of the corporation by himself as Vice-Chairman of the Board of Directors and President.

WITNESS my hand and official seal at office this 27th day of April, 2000.

Notary Public

My commission expires:

May 6, 2001

STATE OF TENNESSEE }
COUNTY OF CAMPBELL }

Personally appeared before me, a Notary Public in the State and County aforesaid, Richard C. Williams, with whom I am personally acquainted, or proved to me on the basis of satisfactory evidence, and who, under oath, acknowledged himself to be the President and CEO of St. Mary's Health System, Inc., the within-named bargainor, a corporation, and that he as such President and CEO being authorized so to do, executed the foregoing instrument for the purposes therein contained, by signing the name of the corporation by himself as President and CEO.

WITNESS my hand and official seal at office this 27th day of April, 2000.

Notary Public

My commission expires:

May 6, 2001

April 27, 2000/ 1:01 pm
S:\RIO\JDO\ST-MARY'S\LAFOLLET\Agreements\4.27.00.fin.wpd
jdo

Exhibits to Original Lease omitted from this copy of the Lease.

EXHIBITS TO LEASE AND PURCHASE OPTION AGREEMENT

Table of Contents

EXHIBIT "B"

Guaranty

GUARANTY

RE: Lease and Purchase Option Agreement between THE CITY OF LAFOLLETTE, TENNESSEE, a city organized and existing as a governmental unit under the laws of the State of Tennessee, (the *"Lessor"*), and LAFOLLETTE MEDICAL CENTER, INC., and MERCY HEALTH PARTNERS, INC. (collectively, the *"Lessee"*), dated April 27, 2000, as amended by that certain First Amendment to Lease Agreement which is anticipated in connection with the assignment of said Lease and Purchase Option Agreement (the *"Lease"*).

FOR VALUE RECEIVED and in consideration for, and as an inducement to the Lessor for entering into the above referenced First Amendment to Lease Agreement to which this Guaranty is attached, the undersigned, jointly and severally, hereby unconditionally guarantee to the Lessor, its successors and assigns, the prompt payment of rent and all other monetary obligations under the Lease (including without limitation attorneys' fees and costs incurred by Lessor in connection with the enforcement of the Lease or this Guaranty) and the full performance and observance of all the covenants, conditions, and agreements therein provided to be performed and observed by the Lessee, its successors and assigns, and expressly agree that the validity of this Guaranty and the obligations of the Guarantor hereunder shall in no wise be terminated, affected, or impaired by reason of the assertion by the Lessor against the Lessee of any of the rights or remedies reserved to the Lessor pursuant to the provisions of the Lease, or by reason of the waiver by the Lessor of, or the failure of the Lessor to enforce, any of the terms, covenants, and conditions of the Lease, or the granting of any indulgence or extension of time to the Lessee, all of which may be given or done without notice to the Guarantor.

The undersigned further covenants and agrees that this Guaranty shall remain and continue in full force and effect as to any amendment, modification, renewal, or extension by the Lessee of the Lease, to all of which the undersigned hereby consents in advance, and as to which the undersigned expressly waives any notices.

Jurisdiction and venue of any action to enforce this Guaranty shall be in Campbell County, State of Tennessee.

IN WITNESS WHEREOF, the undersigned has caused this Guaranty to be duly executed this 1ST day of OCTOBER, 2011.

KNOXVILLE HMA HOLDINGS, LLC, Guarantor

By: _____
Name: Timothy R. Pixley
Title: SR. VICE PRESIDENT

EXHIBIT "C"

Undeveloped Land

SITUATED in District Three of Campbell County, Tennessee, within the corporate limits of the City of LaFollette, Tennessee, and being more particularly bounded and described as follows:

BEGINNING at an iron pin set in the northwest right of way line of New Appalachian Highway (aka Highway 25W, and aka State Route 9), corner to property of University of Tennessee Medical (Deed Book 360, page 85); thence from said beginning point and with the northwest right of way line of New Appalachian Highway, four calls and distances as follows: South 43 deg. 41 min. 27 sec. West, 25.92 feet to a point; South 43 deg. 41 min. 27 sec. West, 265.07 feet to highway monument "C"; North 45 deg. 50 min. 29 sec. West, 5.15 feet to highway monument "B"; and South 43 deg. 21 min. 18 sec. West, 309.50 feet to an iron pin set corner to property being retained by E. F. Wheeler; thence with new severance line with E. F. Wheeler, North 40 deg. 41 min. 26 sec. West, 375.92 feet to an iron pin set; thence continuing with the line of Wheeler, South 43 deg. 23 min. 27 sec. West, 167.10 feet to an iron pin set in the line of property of Robert L. Woodson III (Deed Book 412, page 123); thence with line of Woodson, North 30 deg. 29 min. 19 sec. West, 888.74 feet to an iron pin; thence continuing with said line, North 35 deg. 20 min. 52 sec. West, 20.79 feet to an iron pin in the line of Lot 6A, Big Springs Subdivision; thence with line of Lot 6A and 7A, Big Springs Subdivision, North 47 deg. 25 min. 37 sec. East, 101.84 feet to an iron pin, corner to Lot 8A; thence with the line of Lot 8A, North 56 deg. 59 min. 26 sec. East, 141.00 feet to an iron pin, corner to property of Tennessee State University and Community College (Deed Book 401, page 785); thence with the line of said property, South 37 deg. 16 min. 19 East, 201.12 feet to an iron pin; thence continuing with said line, North 47 deg. 10 min. 06 sec. East, 453.00 feet to an iron pin in the southwest right of way line of Independence Lane; thence with the southwest right of way line of Independence Lane, South 43 deg. 28 min. 40 sec. East, 137.95 feet to an iron pin; thence South 54 deg. 05 min. 09 sec. East, 330.63 feet to an iron pin, corner to property of University of Tennessee Medical (Deed Book 360, page 85); thence with line of said property, three calls and distances as follows: South 54 deg. 14 min. 00 sec. West, 143.98 feet to an iron pin; South 35 deg. 52 min. 01 sec. East, 549.92 feet to an iron pin; and South 30 deg. 20 min. 29 sec. East, 5.34 feet to an iron pin, said iron pin marking the place of BEGINNING; and being according to the survey of Tony W. Crutchfield, Tennessee RLS #1788, of Crutchfield Surveys, P.O. Box 292, Jacksboro, TN 37757, dated September 23, 2005, and revised January 10, 2007.

BEING the same property conveyed to E. F. Wheeler, Jr., by the following deeds:

(1) Deed from Wanda D. Jackson, dated August 14, 1997, of record in Deed Book 348, page 826;

(2) Deed from Joyce D. Webb, dated August 14, 1997, of record in Deed Book 348, page 830; and

(3) Deed from K. Lynn Davis, dated August 30, 2000, of record in Deed Book 374, page 386, all in the Campbell County Register's Office.

(4) Deed from Carlock Myers and wife, Nellie M. Myers, dated February 21, 1998, of record in Deed Book 353, page 21, in the Campbell County Register's Office.

GUARANTY

RE: Lease and Purchase Option Agreement between THE CITY OF LAFOLLETTE, TENNESSEE, a city organized and existing as a governmental unit under the laws of the State of Tennessee, (the *"Lessor"*), and LAFOLLETTE MEDICAL CENTER, INC., and MERCY HEALTH PARTNERS, INC. (collectively, the *"Lessee"*), dated April 27, 2000, as amended by that certain First Amendment to Lease Agreement which is anticipated in connection with the assignment of said Lease and Purchase Option Agreement (the *"Lease"*).

FOR VALUE RECEIVED and in consideration for, and as an inducement to the Lessor for entering into the above referenced First Amendment to Lease Agreement to which this Guaranty is attached, the undersigned, jointly and severally, hereby unconditionally guarantee to the Lessor, its successors and assigns, the prompt payment of rent and all other monetary obligations under the Lease (including without limitation attorneys' fees and costs incurred by Lessor in connection with the enforcement of the Lease or this Guaranty) and the full performance and observance of all the covenants, conditions, and agreements therein provided to be performed and observed by the Lessee, its successors and assigns, and expressly agree that the validity of this Guaranty and the obligations of the Guarantor hereunder shall in no wise be terminated, affected, or impaired by reason of the assertion by the Lessor against the Lessee of any of the rights or remedies reserved to the Lessor pursuant to the provisions of the Lease, or by reason of the waiver by the Lessor of, or the failure of the Lessor to enforce, any of the terms, covenants, and conditions of the Lease, or the granting of any indulgence or extension of time to the Lessee, all of which may be given or done without notice to the Guarantor.

The undersigned further covenants and agrees that this Guaranty shall remain and continue in full force and effect as to any amendment, modification, renewal, or extension by the Lessee of the Lease, to all of which the undersigned hereby consents in advance, and as to which the undersigned expressly waives any notices.

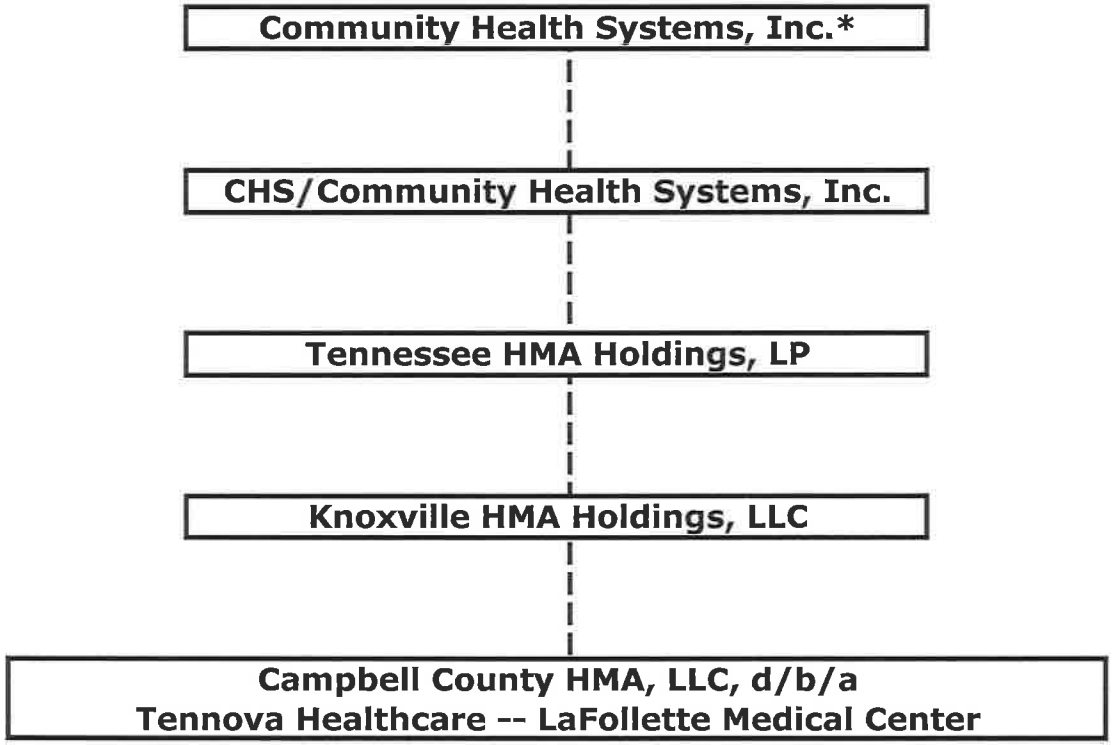
Jurisdiction and venue of any action to enforce this Guaranty shall be in Campbell County, State of Tennessee.

IN WITNESS WHEREOF, the undersigned has caused this Guaranty to be duly executed this 1ST day of OCTOBER, 2011.

KNOXVILLE HMA HOLDINGS, LLC, Guarantor

By: Timothy R Ray
Name: Timothy R. Ray
Title: SR. VICE PRESIDENT

OWNERSHIP OF CAMPBELL COUNTY HMA, LLC, d/b/a TENNOVA HEALTHCARE LAFOLLETTE MEDICAL CENTER



* A publicly traded company

Attachment B, 1

HealthTronics™

August 5, 2015

Kathy Myers, RN
Chief Nurse Officer
LaFollette Medical Center
923 East Central Avenue
LaFollette, TN 37766

Dear Kathy,

The lithotripter, Kentucky I Lithotripsy, LLC, a subsidiary of HealthTronics, Inc, we will be utilizing at your facility is the HealthTronics LithoDiamond. Its estimated FMV would be about $200,000.

Please feel free to contact me with any questions and / or concerns. I am best reached at (330) 283-0035 or via email at Robert.Grimmer@HealthTronics.com.

Best regards,

Robert Grimmer
Area Vice President

MOBILE LITHOTRIPSY SERVICES AGREEMENT

THIS SERVICES AGREEMENT (the "Agreement"), made and entered into this 1st day of July, 2015 (the "Effective Date"), by and between Kentucky I Lithotripsy, LLC, a Kentucky limited liability company ("Provider"), and LaFollette Medical Center ("Hospital").

W I T N E S S E T H

WHEREAS, the Hospital is a general acute care hospital licensed in the State of Tennessee and is in need of purchasing certain lithotripsy services for its patients, which would require a mobile extracorporeal shock wave lithotripter and a technologist operator, and other incidental services and supplies; and

WHEREAS, Provider owns and operates one fully mobile extracorporeal shock wave lithotripter (the "ESL") and provides lithotripsy services related to the operation of the ESL technology through its employed technologist, and desires to enter into an agreement whereby Provider will provide the lithotripsy services under arrangement to Hospital; and

WHEREAS, Hospital desires to contract under arrangement with Provider to purchase the lithotripsy services provided through Provider's ESL and employed technologist, in order to treat Hospital patients at a site located on Hospital premises, under the terms and conditions as hereafter stated; and

WHEREAS, Provider desires to contract with Hospital to provide certain specified facilities and incidental supplies and services to enable Provider to provide the lithotripsy services under arrangement on Hospital premises to Hospital patients, under the terms and conditions as hereafter stated; and

NOW, THEREFORE, in consideration of the premises and the mutual promises herein contained, and other valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Hospital and Provider agree as follows:

1. SERVICES AND SCHEDULING.

1.1 Scheduling. The parties agree that on the dates and times set forth by mutual agreement ("Hospital Days"), Hospital shall be entitled and authorized to have the ESL used, on a first priority basis, to perform "ESL Services" (as defined herein) at Hospital for the benefit of all of its scheduled outpatients and inpatients. In the event there are no procedures scheduled on a Hospital Day, Provider shall have no obligation to transport to or otherwise make the ESL available to Hospital on Hospital premises. Should Hospital request to use the ESL on days or times that are not Hospital Days, Provider shall use reasonable efforts to accommodate Hospital's request, provided that the ESL and ESL personnel are in the area and available. For all purposes under this Agreement, "ESL Services" is the provision of the lithotripsy services provided under

arrangement by Provider at the Hospital premises through the operation of the ESL by the Provider's employed technologist working with an independent physician to perform a medical procedure, and all technical and other services in connection therewith, but excluding any physician professional services.

1.2 Categories of Use. Hospital engages Provider to provide under arrangement all the services outlined in this Agreement to all of the Hospital ESL patients whose health care services are reimbursable under any state or federal benefit program (including the Medicare Program, the Medicaid Program and TRICARE), as well as the Hospital ESL patients for which ESL Services are reimbursable under a health care plan by a health maintenance organization, insurance company, self-insured employer or other third party payor, or self-payor. Provider shall provide these services in accordance with the schedule agreed upon pursuant to this Agreement.

1.3 Under Arrangements. The parties intend for the ESL Services provided pursuant to this Agreement be provided by Provider "under arrangement" to the Hospital as defined by the Social Security Act (the "Act"), including Sections 1832(a) and 1835(b) of the Act, and to otherwise comply with all applicable statutory and regulatory requirements as established from time to time by the Centers for Medicare & Medicaid Services ("CMS") or the federal or state governments relating to services provided by hospitals under arrangements by others. At all times Provider shall retain dominion and control of the ESL and its employed technician, and will arrange for all other related items, supplies and personnel, if any, required for the performance of the ESL Services. The Hospital shall not exercise control over the ESL or technologist as a lessee of equipment or personnel. As provided herein, the Hospital shall provide the facility and certain incidental supplies and services in furtherance of Provider's provision of ESL Services, and the Hospital shall be remunerated therefore as provided in Section 5 herein.

2. INDEPENDENT CONTRACTOR. Notwithstanding any other provision of this Agreement, it is specifically understood and agreed that the activities and undertakings of the Provider in the performance of services under this Agreement shall be as an independent contractor and not as an employee of the Hospital or lessor to the Hospital. The Hospital shall not exercise any control or direction over the methods by which Provider performs its services hereunder; the sole interest and responsibility of the Hospital is to assure that the services provided by the Provider under this Agreement shall be performed and rendered in a competent, efficient, and satisfactory manner.

3. HOSPITAL RESPONSIBILITIES. In consideration of the receipt of the Hospital remuneration set forth in Section 5, and in furtherance of the provision of ESL Services by Provider, the Hospital agrees to provide on its premises all usual and customary hospital services and supplies as ordered by the treating urologists or other supervising physician, except as otherwise provided by Provider in Section 4 herein, including, but not limited to the following:

a. Provide and have sole responsibility for the registration of all of the Hospital ESL patients to be treated at the ESL Site (as defined herein), including ensuring that each Hospital ESL patient who arrives for treatment utilizing the ESL has in his or her possession a written authorization from a physician for lithotripsy treatment and such other forms, consents or information as Provider and Hospital may reasonably deem necessary;

b. A pregnancy test for all menstruating females, as well as all lab work required by the Hospital and as requested by the treating urologist;

c. The designation and use of a suitable specific site for the location and use of the ESL including a pre-procedure and post-procedure area for each Hospital ESL patient (the "ESL Site");

d. The provision of all utilities required for use of the ESL while located at the ESL Site, including electricity, telephone, water and waste disposal;

e. For each ESL procedure, to the extent medically necessary, and as ordered by the treating urologist, all necessary medical disposables and supplies, including, without limitation, the provision of I.V. fluid, I.V. tubing and necessary attachments, intravenous catheter ("Intracath"), sedation or anesthesia supplies and drugs, oxygen, an EKG, I.V. antibiotics, the use of Hospital's contrast material, as necessary, linens, chart forms, urinal, urine strainer, specimen pan, and emesis pan;

f. Coordinating the provision of physician professional services (other than urology) necessary for each ESL procedure, such as radiology, pathology, and anesthesiology, to be provided by physicians with the appropriate Hospital privileges in the specialties required for the ESL procedures; provided, however, that in accordance with Section 6.3 hereof, Hospital shall not be responsible for any costs or expenses in connection with the performance of such physician professional services;

g. Arranging for, and maintaining, all necessary statutory requirements, and compliance with all applicable regulatory approvals for the provision of ESL Services at the ESL Site;

h. In the event that a Hospital ESL patient treated at the ESL Site requires, in the opinion of the attending physician, evaluation in or admission to the Hospital's Emergency Department or other acute setting, Hospital shall arrange for the immediate transportation of the patient from the ESL Site, for evaluation and treatment as medically appropriate, and admit the patient to appropriate services at the Hospital in accordance with Hospital policies, procedures, and bylaws. Hospital acknowledges that Provider is not responsible for any charges or for any act or omission of Hospital or its agents attributable to the transportation, diagnosis or treatment of the transferred patient;

i. Review and monitor all ESL Services provided hereunder in accordance with Hospital's Utilization Review Committee's policies and procedures and the Hospital's under arrangement contracting responsibilities;

j. While the ESL is in operation at the ESL Site, Hospital shall assign a qualified operating room registered nurse to provide services exclusively for ESL Services. Hospital shall make available Hospital personnel as medically necessary to respond to medical emergencies occurring at the ESL Site. Hospital shall also schedule a certified registered nurse anesthetist or anesthesiologist to administer anesthesia, as per Hospital policy or medical staff regulations; and

k. Billing and collection services for all of the ESL procedures shall be the sole responsibility of the Hospital as further detailed in Section 6 below.

4. PROVIDER RESPONSIBILITIES In consideration of the receipt of the Provider compensation as set forth in Section 5, Provider agrees to provide the following related to its provision of the ESL Services:

a. Transportation of the ESL to and from Hospital, provide and maintain the ESL, and all related equipment in good working order for use at the ESL Site on each Hospital Day;

b. All delivery and setup services for Provider's operation of the ESL at the ESL Site;

c. All maintenance services and parts in connection with the maintenance of the ESL without regard to the cause for the need therefor, and provide maintenance reports to the Hospital upon request;

d. Responsibility for all licensing or certification requirements, if any (whether state, federal or local) in connection with the ownership and operation of the ESL. Upon reasonable request, Provider shall produce documentation of such licensure or certification to the Hospital;

e. Creating and maintaining a quality assurance program for monitoring and improving the efficacy of the operation of the ESL and the ESL Services provided by Provider on Hospital premises, and complying with all applicable standards of The Joint Commission (TJC) and Medicare standards, including the applicable Medicare conditions of participation for hospital contracted services currently specified at 42 CFR 482.12(e). Provider shall cooperate with Hospital's quality assurance committee in its periodic review, on a random sample basis, of services provided to Hospital patients by Provider pursuant to the terms of this Agreement. Quality assurance reports may be requested by mailing the request to the address as indicated below. Quality assurance reports will include quality assurance activities conducted;

Quality Assurance Report Requests:
Kentucky I Lithotripsy, LLC
Attn: Quality Assurance Department
9825 Spectrum Drive, Building 3
Austin, Texas 78717
Phone: 888-252-6575

f. A radiologic technologist trained in ESL Services and operation of the ESL, who shall assist the attending urologist or other physician in performance of the lithotripsy procedures. The radiologic technologist shall perform all ESL Services in accordance with the Provider's policies, procedures, and guidelines approved by the Provider and its physician owners, as well as all Hospital rules, regulations, procedures, policies and bylaws, and the Hospital medical staff rules, regulations, procedures, policies and bylaws to the same extent such would be applicable to Hospital's own personnel. If requested by Hospital, Provider shall provide information and documentation regarding licensure, certification, training, and experience of the radiologic technologist;

g. At Hospital's request, participate in Hospital's utilization review program and any other Hospital program or committee with respect to the ESL Services that would be required if the ESL services were furnished directly by the Hospital. Furthermore, Provider shall meet with Hospital management as appropriate and necessary on a periodic basis to discuss pertinent issues relating to the arrangement and/or ESL services;

h. Prompt submittal of written reports of all examinations, treatments and procedures performed pursuant to this Agreement to Hospital's medical records administrator, and, if appropriate, to the patient's private physician. Provider shall use the medical records and reports forms provided by Hospital. Provider agrees that all records and reports required by this Section shall be the exclusive personal property of Hospital. Provider shall have the right to photocopy any such records or reports for inclusion in its records; and

i. Comply with Hospital policies and other required guidelines aimed at ensuring the accurate and safe operation of the ESL, including policies regarding biomedical inspection of the ESL, radiation physicist inspection of the ESL, and any state certifications concerning the imaging component of the ESL. Any inspection reports or state certifications would be made available to the Hospital upon request.

5. COMPENSATION.

5.1 Provider Compensation. In consideration of Provider performing the ESL Services, including the performance of all of its obligations under Sections 1.1 and 4 of this Agreement in the treatment of all of the Hospital ESL patients as provided in Section 1.2 herein, Hospital shall pay to Provider a fee in accordance with Exhibit A (the "Provider Fee"). The Provider Fee shall be due and payable by Hospital to Provider

at the payment address (the "Payment Address") of Provider as herein provided within thirty (30) days of the end of the month in which the services were provided.

Provider Payment Address:
Kentucky I Lithotripsy, LLC
PO Box 95333
Grapevine, TX 76099-9732

5.2 Fair Market Value. The parties hereto acknowledge and agree that the Provider Fee is consistent with fair market value without regard for referrals or business generated between the parties and that such fees are commercially reasonable to accomplish the business purposes of the parties. The parties further acknowledge and agree that the aggregate Provider Fees are less than the full aggregate amounts collected by the Hospital (as provided in Section 6 below) for the purchased ESL Services in order to appropriately account for the value of the services provided by the Hospital as set forth in Sections 3 and 6 herein.

6. BILLING AND COLLECTIONS.

6.1 Hospital Services Billing and Collections. All ESL Services under Section 1.2 shall be billed to and collected from such payors and patients exclusively by Hospital, and Hospital shall retain for its own account all amounts collected for such services.

6.2 Other Patient Services. The parties agree that this Agreement covers only ESL Services to Hospital ESL patients and that all other patient services are specifically excluded from the terms of this Agreement. Except as otherwise specifically provided in this Agreement, Hospital shall have the exclusive right to bill and collect for all hospital services rendered to its patients.

6.3 Physician Professional Services. Neither Provider nor Hospital shall be responsible for billing and collecting for any physician professional services performed in connection with the use of the ESL. The parties agree that all such professional services are specifically excluded from the terms and provisions of this Agreement. Furthermore, all fees for physician professional services rendered in connection with the furnishing of any radiology, pathology and anesthesiology services relating to the use of the ESL are likewise specifically excluded from the terms of this Agreement, it being agreed and understood by the parties that neither party shall have any responsibility for the billing and collection of such services.

6.4 Accounting Procedures. Hospital shall maintain complete books and records of the billings, collections, disbursements, and expenses of the ESL operations, as provided herein, in accordance with generally accepted accounting principles, with correct entries of all receipt and expenditures, which books of account shall be the property of the Hospital, but upon reasonable notice shall be open to the inspection of the Provider or its duly authorized agents. Provider shall have the right to

audit the Hospital's books and records, as it relates to this Agreement, for any period, during normal business hours, upon reasonable notice, at any time during the three calendar years following the submission by Hospital of any monthly report or annual statement for such period.

7. TERM AND TERMINATION.

7.1 Term. This Agreement shall commence on the Effective Date and shall continue for an initial term of one (1) year (the "Initial Term"). Thereafter, unless otherwise terminated as herein provided, this Agreement shall be automatically renewed for successive one year terms (each a "Renewal Term"). Notwithstanding the foregoing provisions, this Agreement may be terminated by either party at the end of the Initial Term or any Renewal Term by the delivery of a written notice to the other party advising such other party of the intention to terminate this Agreement at least 90 days prior to the contract date of termination.

7.2 General For Cause Termination. Except as otherwise provided in this Agreement, in the event of a breach of a material term of this Agreement by either party, the non-breaching party may deliver written notice to the breaching party identifying the nature of the breach, whereupon (i) if the breach relates to any payment obligation under this Agreement, the breaching party shall have a period of 15 days after the receipt of such notice to cure such breach or (ii) for any other breach other than a payment obligation, the breaching party shall have a period of 30 days after receipt of such notice to cure such breach or, in the event that such breach cannot be reasonably cured within such 30 day period, then for an additional 30 day period as is reasonably necessary to cure such breach and provided that the breaching party engages in continuous, diligent, and good faith efforts to cure such breach. In the event that any breach is not cured within the time, as applicable, as provided above, the non-breaching party shall have the right to terminate this Agreement by the delivery of a second written notice to the breaching party of such termination whereupon this Agreement shall terminate immediately upon the delivery of such second written notice.

7.3 Termination For Cause Based Upon Changes In Reimbursement Laws. If changes in reimbursement laws or regulations (or the interpretations thereof) occur during the term of this Agreement which materially and adversely affect third party reimbursement of Hospital, the Hospital may request renegotiation of the applicable terms of this Agreement by written notice to the other party. The parties agree to negotiate in good faith to amend this Agreement to conform with such laws and regulations and to minimize the adverse effects of such laws and regulations. In the event that no new agreement can be reached within 60 days after receipt of such notice (or such earlier time as may be required by such law or regulation), then either party may immediately terminate this Agreement by the delivery of written notice to the other party.

7.4 Termination For Cause Based On Federal Or State Law. Notwithstanding other provisions of this Agreement to the contrary, in the event that either party shall reasonably determine based on the written opinion of a qualified law

firm representing either party that the continued performance of this Agreement is in violation of any federal or state laws, regulations, rulings or cases, the parties agree that, on receipt by a party from the other party of a written notice which, includes the written opinion of outside counsel, specifically identifying the violation or violations, the performance of all obligations hereunder by the parties to each other shall be immediately suspended and the parties shall immediately enter into good faith negotiations to reform all such provisions of this Agreement identified in the notice. If the parties have not been able to agree, within 30 days after the delivery of the notice, upon the reformation of this Agreement in a manner so as to cure such violation or violations, either party shall have the right to terminate this Agreement effective immediately upon the delivery of written notice thereof to the other party which termination shall not be a breach of this Agreement.

7.5 Effect Of Termination. As of the effective date of termination of this Agreement, neither party shall have any further rights or obligations hereunder except: (a) as otherwise provided herein; (b) for rights and obligations accruing prior to such effective date of termination; or (c) arising as a result of any breach of this Agreement.

8. INDEMNIFICATION AND INSURANCE.

8.1 Indemnification by Hospital. To the fullest extent permitted by law, Hospital agrees to indemnify and hold harmless Provider and all of its corporate members, directors, officers, partners, agents and employees (for the purpose of this Section, the "Provider Indemnified Parties") from and against all claims, damages, losses, and expenses, including but not limited to attorney's fees and court costs, arising out of, resulting from, or relating to the performance of, or the failure to perform, Hospital's obligations as provided in this Agreement, and from any claim, damage, loss, or expense which is attributable to bodily injury, sickness, disease, death, or injury to, or destruction of, tangible property including the loss of use resulting therefrom, but only to the extent caused by the acts, omissions or negligence of Hospital or anyone directly or indirectly employed by Hospital or anyone for whose acts Hospital may be liable (except the Provider Indemnified Parties). The provisions of this Section shall survive the termination of this Agreement.

8.2 Indemnification by Provider. To the fullest extent permitted by law, Provider agrees to indemnify and hold harmless Hospital and all of its corporate members, trustees, officers, agents and employees (for the purposes of this Section, the "Hospital Indemnified Parties") from and against all claims, damages, losses, and expenses, including but not limited to attorney's fees and court costs, arising out of, resulting from, or relating to the performance of, or the failure to perform, Provider's obligations as provided in this Agreement, and from any claim, damage, loss or expense which is attributable to bodily injury, sickness, disease, death, or injury to, or destruction of, tangible property including the loss of use resulting therefrom but only to the extent caused by the acts, omissions or negligence of Provider or anyone directly or indirectly employed by Provider or anyone for whose acts Provider may be liable (except the

Hospital Indemnified Parties). The provisions of this Section shall survive the termination of this Agreement.

8.3 Insurance.

a. Provider, at its sole cost and expense, shall procure and maintain such policies of comprehensive general liability insurance, professional liability and other insurance as shall be necessary to insure Provider and its partners, agents and employees against any claim or claims for damages arising by reason of personal injury or death occasioned directly or indirectly in connection with the provisions of any services hereunder by Provider, the use of Provider property and facilities or the activities of Provider, its partners, agents or employees in connection with the performance of this Agreement or otherwise.

b. Hospital, at its sole cost and expense, shall procure and maintain such policies of comprehensive general liability insurance, professional liability, and other insurance as shall be necessary to insure Hospital and its officers, agents, and employees against any claim or claims for damage arising by reason of personal injury or death occasioned directly or indirectly in connection with the provisions of any services hereunder by Hospital, the use of Hospital property and facilities or the activities of Hospital, its officers, agents, or employees in connection with the performance of this Agreement or otherwise.

c. Such policies of insurance, unless the parties hereto shall agree otherwise in writing, shall be in limits of not less than $1,000,000 dollars per person for personal injury or death and not less than $3,000,000 dollars per occurrence. Upon request, either party shall furnish certificates of insurance indicating coverage to the other party. Both parties agree to notify the other party immediately upon notification from the insurance carrier that such policies may be canceled.

9. EXCLUSIVE PROVISION OF LITHOTRIPSY SERVICES. Hospital agrees that, during the term of this Agreement, Provider will be the exclusive provider of lithotripsy services at Hospital, and that during the term of this Agreement, Hospital will not contract with another provider of lithotripsy services nor shall it acquire, lease or undertake the provision of lithotripsy services directly or indirectly in its own name or through a subsidiary.

10. JOINT APPROVAL OF UROLOGIST OPERATORS. Physicians seeking to use Provider's ESL for the treatment of Hospital ESL patients must be Board certified or Board-eligible urologists, members of the Hospital medical staff in good standing with privileges in urology, and approved by Provider, before being allowed access to the ESL. Provider shall not unreasonably withhold access to the ESL or ESL Services from any Board certified or Board eligible urologist who is a member in good standing of the Hospital medical staff with privileges in urology. Provider will comply with the quality assurance requirements of Hospital.

11. ACCESS TO BOOKS AND RECORDS. For a period of four years after the furnishing of the services as stated in this Agreement, both Provider and Hospital shall make available, upon written request by the Secretary of Health and Human Services or upon request by the Comptroller General, or any of their duly authorized representatives, the contract, and books, documents, and records of Provider and Hospital that are necessary to certify the nature and extent of the cost under this Agreement, and, if Provider or Hospital carries out any of their duties under this Agreement through a subcontract, with a value or cost of $10,000 or more over a 12-month period with a related organization, such subcontract shall contain a clause to the effect that until the expiration of four years after the furnishing of such services pursuant to such subcontract, the related organization shall make available upon written request by the Secretary of Health and Human Services, or upon representatives, the subcontract, and books, documents, and records of such organization that are necessary to verify the nature and extent of such costs.

12. NONDISCLOSURE OF PROPRIETARY INFORMATION.

(a) The parties acknowledge and agree that during the term hereof each shall have access to Confidential Information (as defined below) and other proprietary information of the other party which shall be deemed to be confidential. To the extent permitted by law, both parties shall not, nor shall their respective employees and agents, except as may be required by any lawful subpoena, court order or legal process, at any time without the other party's prior written consent: (i) disclose any such information to any third party, or (ii) reproduce or utilize any such information in furtherance of any other business venture. If either party is required by lawful subpoena, court order, or legal process to disclose any Confidential Information or other proprietary information (the "Disclosing Party") of the other party, the Disclosing Party shall provide sufficient notice thereof to the other party to enable the other party to seek a protective order or other appropriate legal or equitable remedy to prevent such disclosure. Each party shall also keep medical records of the Hospital confidential in accordance with all applicable state and federal laws. For purposes of this Section, the term "Confidential Information" shall mean the non-public information of a party, or any entity with which a party contracts to provide any of the ESL Services, including, but not limited to, a formula, pattern, compilation, program, device, method, system, technique, process, financial information, business strategy, or costing data, patient list, payor list, manuals, policies and procedures, forms, contractual arrangements, etc. Confidential Information shall not include information which: (i) is known to the receiving party prior to receiving it from the other party, (ii) is generally known to the public; or (iii) is disclosed to one party at any time by a third party who had the legal right to disclose it. The provisions of this Section shall survive the termination of this Agreement.

(b) The parties acknowledge that the restrictions in this Section are reasonable and necessary to protect the legitimate interests of the parties and that any violation would result in irreparable injury to the non-disclosing party. The parties further acknowledge that, in the event of a violation of any such restrictions the non-disclosing party shall, in addition to any other rights or remedies to which the non-

disclosing party may be entitled to at law or in equity, be entitled to preliminary and permanent injunctive relief without having to prove actual damages or immediate or irreparable harm or to post a bond. Notwithstanding the foregoing, if the restrictions specified in this Section are adjudged unreasonable in any court proceeding, the parties hereby agree to the reformation of such restriction by the court to such limits as it finds reasonable, and neither party will assert that such restrictions should be eliminated in their entirety by such court.

13. GENERAL PROVISIONS.

13.1 Amendment. This Agreement may be amended, changed, waived, discharged, or terminated only by an instrument in writing signed by the party against which enforcement of the amendment, change, waiver, discharge, or termination is sought.

13.2 Authorization to Make Agreement. Each person signing this Agreement on behalf of a party personally represents and warrants to the other party that the execution and performance of this Agreement is duly authorized by the party's governing board or other body authorized to make or authorize agreements on behalf of the party, that this Agreement is not in conflict with any prior contract of the party, and that this Agreement constitutes a valid obligation of each party, enforceable according to its terms.

13.3 Compliance with Applicable Law, Licenses, Etc. The parties will each comply with all applicable statutes, laws, rules, regulations, licenses, certificates, and authorization of any governmental body or authority in the performance or carrying out of its obligations under this Agreement. This Agreement shall be subject to amendments in the applicable laws and regulations relating to the subject matter of this Agreement, but only to the extent that any inconsistency is thereby created, and the parties shall use their best efforts to accommodate both the terms and intent of this Agreement and of such amendments. Each party will obtain and maintain current and in force all licenses, certifications, authorizations, and/or permits (and will pay the fees therefore) necessary to carry out its duties and responsibilities under this Agreement.

13.4 Referrals. The parties acknowledge that Provider is an Kentucky limited liability company consisting in part of physician members who treat patients with kidney stone disease and who may refer ESL and other patients to Hospital. The parties further acknowledge that none of the benefits granted Provider hereunder are conditioned on any requirement that Provider, or its physician members, make referrals to, be in a position to make or influence referrals to, or otherwise generate business for Hospital. The parties further acknowledge that Provider's physician members are not restricted from referring any patient to, or otherwise generating any business for, any other medical facility of his/her choosing.

13.5 Subcontracts and Assignment. Except as otherwise specifically provided in this Section, this Agreement and the rights and obligations created hereunder

shall not be assignable nor performable by subcontract by either party without the prior written consent of the other party, which consent the other party agrees not to unreasonably withhold in its reasonable business judgment. This Agreement shall nevertheless be freely assignable and transferable by either party to any affiliate and freely performable by subcontract with any affiliate. For purposes of this Section 13.5, the term "affiliate" means any entity directly or indirectly controlling, controlled by or under common control with such party.

13.6 Entire Agreement, Binding Effect. This Agreement contains the entire Agreement and understanding between the parties and it supersedes all prior Agreements, understandings, and representations relating to the subject matter of this Agreement. This Agreement shall be binding upon the parties and their representatives, successors, and assigns.

13.7 Force Majeure. Neither party shall incur any liability to the other party, nor shall either party be entitled to terminate this Agreement if the performance by either party of its obligations under this Agreement is prevented or delayed by act of God, the public enemy, earthquakes, fires, epidemics, civil insurrections, curtailment of or failure to obtain sufficient electrical power, strikes, lockouts, or similar unforeseen and unusual circumstances beyond the control and without the fault of such party. Any party claiming any such excuse for non-performance shall use its best efforts to avoid or remove such cause, shall continue performance to the degree possible and as soon as possible, and shall give prompt written notice to the other party of the situation.

13.8 Good Faith. Each party agrees to carry out all its responsibilities, duties, and activities under this Agreement in good faith.

13.9 Governing Law. This Agreement shall be construed in accordance with and governed by the laws of the State of Texas, without giving effect to the choice of law provisions thereof.

13.10 No Rights in Third Parties. Unless otherwise expressly stated herein, this Agreement shall not create any rights in or inure to the benefit of any third parties.

13.11 Non-Discrimination. In connection with the rendering of ESL Services under this Agreement, Provider agrees that it shall not discriminate in connection with the provision of such services for or against any person on the basis of age, race, sex, color, religion, creed or national origin.

13.12 Notices. Any notice required or permitted to be given under this Agreement shall be in writing and shall either be personally delivered or sent postage prepaid, by certified mail, return receipt requested, to the address of the parties indicated below or to such other address as either party shall designate by notice to the other party. Such notice shall be effective when actually received or two days after deposit in the U.S.

Postal Service, whichever occurs first. Notices to the parties shall be addressed as follows:

Provider:
Kentucky I Lithotripsy, LLC
9825 Spectrum Drive
Attn: Legal Department, Bldg 3
Austin, Texas 78717

Hospital:
LaFollette Medical Center
923 East Central Avenue
Attn: Legal Counsel
LaFollette, Tennessee 37766

13.13 Section Headings. The section headings designations used in this Agreement are for convenience of reference only, and shall not in any way be construed to modify or restrict any of the terms or provisions hereof.

13.14 Taxes. Each party shall be responsible for the payment of any and all federal, state, or local taxes which may arise or be imposed as the result of its performance under this Agreement or as the result of the receipt of any compensation or other funds under this Agreement, if any.

13.15 Waiver. No failure by either party to insist upon the strict performance of any term hereof or to exercise any right, power, or remedy following a breach of this Agreement or any term or condition hereof, shall constitute a waiver of any such term or of any such breach. No waiver of any particular breach shall affect or alter this Agreement, which shall continue in full force and effect with respect to any other then existing or subsequent breach.

13.16 Multiple Counterparts. This Agreement may be executed in a number of identical counterparts and each of such shall be deemed for all purposes to be an original, all of which shall constitute, collectively, this Agreement; but in making proof of this Agreement, it shall not be necessary to produce or account for more than one counterpart.

13.17 Provider Representation and Warranty. Provider represents and warrants to Hospital that Provider, its affiliates, or any Provider personnel: (i) is not currently excluded, debarred, or otherwise ineligible to participate in the Federal health care programs as defined in 42 U.S.C. § 1320a-7b(f) (the "Federal health care programs"); (ii) is not convicted of a criminal offense related to the provision of healthcare items or services; and (iii) is not under investigation or otherwise aware of any circumstances which may result in Provider being excluded from participation in the Federal health care programs. This shall be an ongoing representation and warranty during the term of this Agreement, and Provider shall immediately notify Hospital of any change in the status of the representation and warranty set forth in this Section. Any breach of this Section shall give Hospital the right to terminate this Agreement immediately for cause.

IN WITNESS WHEREOF, this Agreement has been executed the day and year first above written.

PROVIDER:
Kentucky I Lithotripsy, LLC

By: Prime Kidney Stone Treatment, Inc., its manager

By: _____
Gary J. Kozen
Vice President

Date: _____

HOSPITAL:
LaFollette Medical Center

By: _____

Name: _____

Title: _____

Date: _____

Exhibit A
Fee Schedule

Fees for ESL Services shall be according to the following schedule:

Lithotripsy: $2,400 per procedure

For purposes of this Exhibit A, a "procedure" is defined as any actual treatment or procedure with the ESL of a patient's medical condition, whether or not the procedure or treatment successfully treats the condition for which it is intended. Each successive or additional treatment or procedure of the same patient at a different time or session shall constitute a separate patient procedure. Treatment of bilateral stones constitutes one and a half procedures. Treatment of a stone in the kidney and a distal stone also constitutes one and a half procedures.

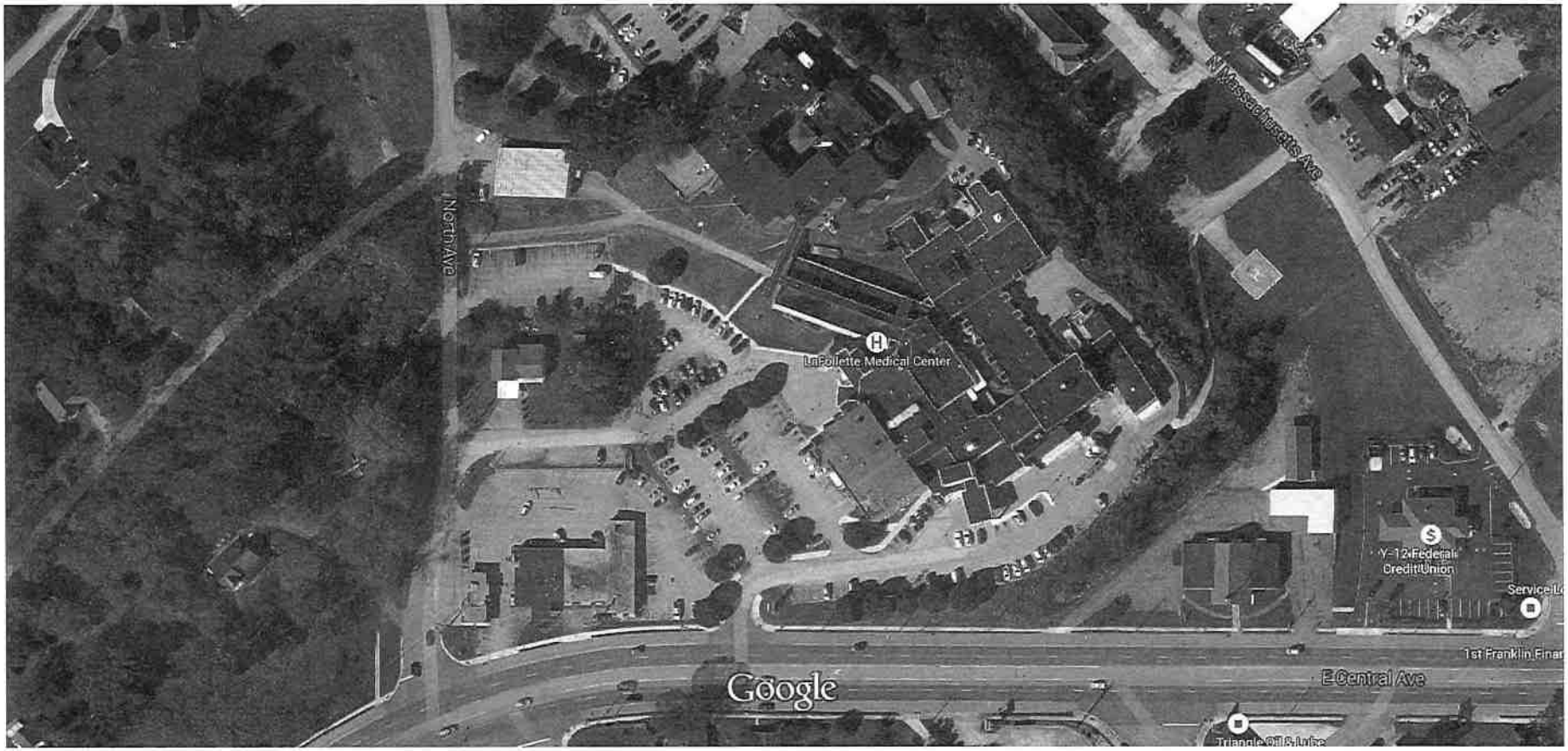
The Provider Fee set forth on this Exhibit A shall be subject to a one time increase at the commencement of each anniversary date equal to the aggregate increase in the Consumer Price Index during the prior twelve completed calendar months immediately preceding the beginning of the anniversary date. The Consumer Price Index referred to above means the United States Department of Labor, Bureau of Labor Statistics, Consumer Price Index U.S. City Average – All Urban Customers – Medical Services.

Provider Initials:_____

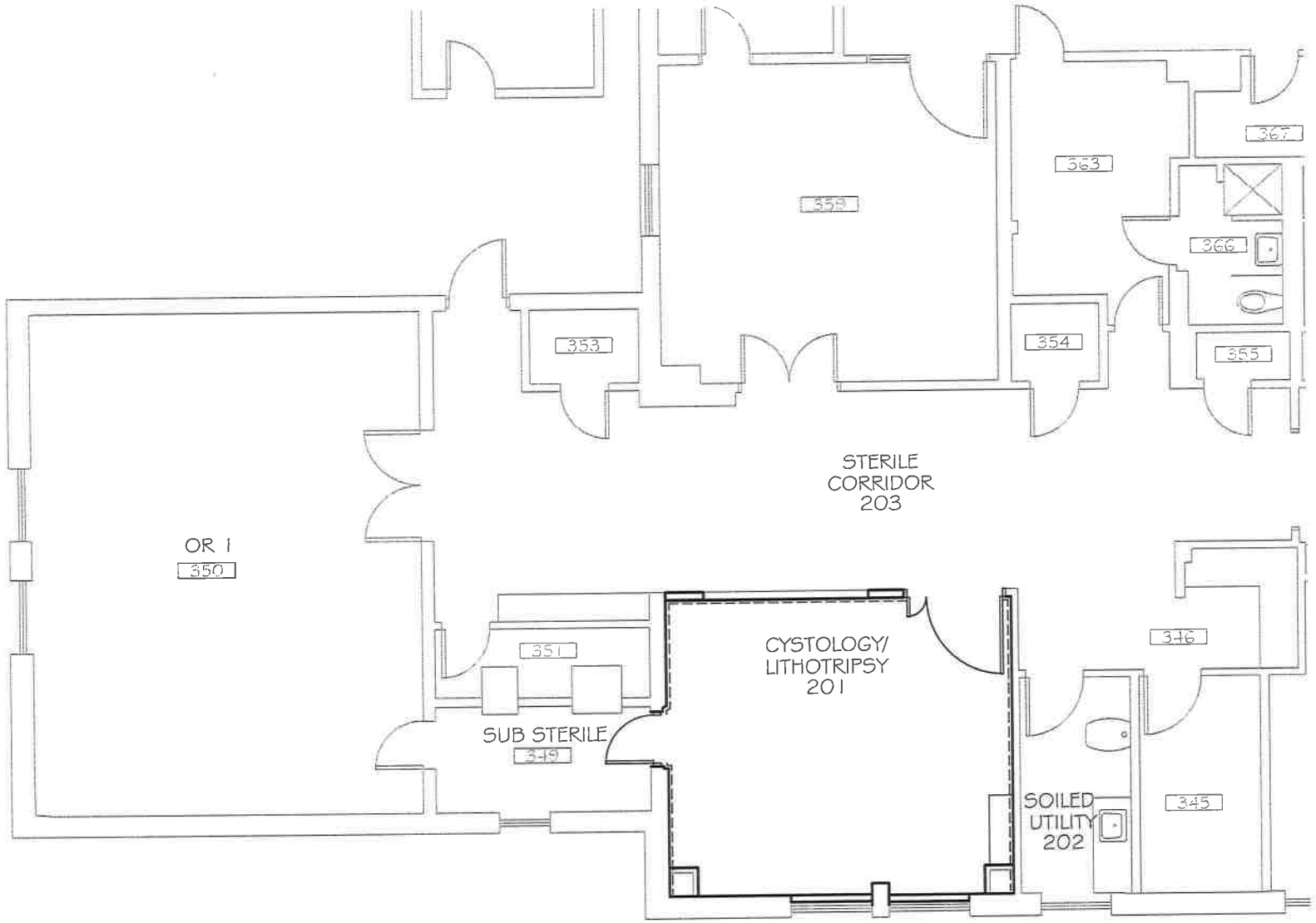
Hospital Initials:_____

Attachment B, III

Google Maps



Imagery ©2015 Google, Map data ©2015 Google 100 ft



Attachment B, IV

EXTRA-CORPOREAL SHOCK WAVE LITHOTRIPSY NEED PROJECTIONS BY COUNTY AND STATE TOTAL, 2014 DATA, PROJECTED TO 2018

STATE UTILIZATION RATE 0.0012927

COUNTY	PROJ POP	NEED
TENNESSEE	6,962,031	9,000
ANDERSON	78,387	101
BEDFORD	51,672	67
BENTON	16,711	22
BLEDSOE	13,394	17
BLOUNT	136,505	176
BRADLEY	107,651	139
CAMPBELL	41,654	54
CANNON	14,658	19
CARROLL	28,298	37
CARTER	58,274	75
CHEATHAM	41,269	53
CHESTER	18,633	24
CLAIBORNE	34,263	44
CLAY	7,876	10
COCKE	37,335	48
COFFEE	56,909	74
CROCKETT	14,982	19
CUMBERLAND	63,778	82
DAVIDSON	698,061	902
DECATUR	12,029	16
DEKALB	19,936	26
DICKSON	54,959	71
DYER	39,607	51
FAYETTE	46,608	60
FENTRESS	19,082	25
FRANKLIN	42,395	55
GIBSON	51,934	67
GILES	29,787	39
GRAINGER	24,244	31
GREENE	73,620	95
GRUNDY	13,379	17
HAMBLEN	66,195	86
HAMILTON	362,471	469
HANCOCK	6,981	9
HARDEMAN	27,284	35
HARDIN	26,680	34
HAWKINS	59,311	77
HAYWOOD	18,274	24
HENDERSON	29,836	39
HENRY	33,771	44
HICKMAN	26,876	35
HOUSTON	9,014	12
HUMPHREYS	19,090	25
JACKSON	12,251	16
JEFFERSON	57,073	74
JOHNSON	18,952	24
KNOX	477,780	618
LAKE	8,441	11
LAUDERDALE	28,930	37
LAWRENCE	43,518	56
LEWIS	12,912	17
LINCOLN	35,104	45
LOUDON	56,118	73
MCMINN	55,100	71
MCNAIRY	27,486	36
MACON	23,838	31
MADISON	104,799	135
MARION	28,627	37
MARSHALL	33,885	44
MAURY	90,666	117
MEIGS	12,345	16
MONROE	49,048	63
MONTGOMERY	211,602	274
MOORE	6,923	9
MORGAN	23,848	31
OBION	31,625	41
OVERTON	23,885	31
PERRY	8,362	11
PICKETT	5,237	7
POLK	17,627	23
PUTNAM	81,972	106
RHEA	34,582	45
ROANE	55,990	72
ROBERTSON	76,231	99
RUTHERFORD	337,990	437
SCOTT	23,058	30
SEQUATCHIE	16,399	21
SEVIER	104,829	136
SHELBY	970,212	1,254
SMITH	20,534	27
STEWART	14,210	18
SULLIVAN	159,393	206
SUMNER	184,532	239
TIPTON	69,239	90
TROUSDALE	8,564	11
UNICOI	19,003	25
UNION	20,124	26
VAN BUREN	5,668	7
WARREN	41,167	53
WASHINGTON	137,400	178
WAYNE	17,551	23
WEAKLEY	36,300	47
WHITE	28,037	36
WILLIAMSON	225,526	292
WILSON	133,865	173

DATA SOURCES: HEALTH SERVICES AND DEVELOPMENT AGENCY EQUIPMENT REGISTRY, as of Aug 10, 2015.
HEALTH STATISTICS POPULATION ESTIMATES 2014.
UNIVERSITY OF TENNESSEE, CENTER FOR BUSINESS AND ECONOMIC RESEARCH 2010-2030 POPULATION PROJECTIONS (2015 VERSION).

PREPARED BY: TENNESSEE DEPARTMENT OF HEALTH, DIVISION OF POLICY, PLANNING AND ASSESSMENT, OFFICE OF HEALTH STATISTICS. Run: Aug 2015

Attachment C, I, Need 1 (1)

Lithotripsy - 2013		
County	**Hospital Name**	**Total**
Campbell	Fort Sanders Regional Medical Center	*
	Methodist Medical Center of Oak Ridge	19
	North Knoxville Medical Center	24
	Parkwest Medical Center	*
	Physicians Regional Medical Center	*
	The University of Tennessee Med. Cntr.	28
Campbell Total		**81**
Claiborne	Fort Sanders Regional Medical Center	*
	Franklin Woods Community Hospital	*
	North Knoxville Medical Center	*
	Parkwest Medical Center	*
	Physicians Regional Medical Center	*
	The University of Tennessee Med. Cntr.	14
Claiborne Total		**31**
Scott	Fort Sanders Regional Medical Center	*
	Methodist Medical Center of Oak Ridge	21
	North Knoxville Medical Center	*
	Physicians Regional Medical Center	*
	The University of Tennessee Med. Cntr.	*
Scott Total		**36**

Note:

* Data is suppressed when the number of visits is less than 11

(1)Lithotripsy is identified by Lithotripsy flag and/or CPT code 50590

Data Source: Tennessee Department of Health, Division of Policy, Planning and Assessment. Hospital Disc

Tennova Healthcare

Melanie M. Hill
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building, Ninth Floor
502 Deaderick Street
Nashville, TN 37243

Re: Tennova Healthcare -- LaFollette Medical Center
CON application for Lithotripsy

Dear Ms. Hill:

I am a board certified Urologist and I have recently joined the medical staff of LaFollette Medical Center, having relocated by practice from Somerset, Kentucky. The proposed establishment of a lithotripsy service at LMC would be of tremendous benefit to pateints in need of this health care service.

I have performed lithotripsy treatments for hundreds of patients, and I know the benefit of early and effective treatment. Renal stones are extremely painful to the patient. Requiring patients to forego or unduly delay treatment not only prolongs suffering, it can lead to further healthcare complications.

I urge you to approve this certificate of need, so we can bring this service to a currently un-served area. Thank you for your consideration.

Sincerely,

Sean DeLair, Urologist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2002

Mr. Peter Weiman
Manager of Clinical Programs
HealthTronics, Inc.
1841 West Oak Parkway
MARIETTA GA 30062

Re: K021775
Trade/Device Name: HealthTronics LithoDiamond (ESWL) Lithotripter (LTF0230)
Regulation Number: 21 CFR §876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: 78 LNS
Dated: September 25, 2002
Received: September 27, 2002

Dear Mr. Weiman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K021775

Device Name: LithoDiamond

Indications for Use:

The LithoDiamond is indicated for use in patients with renal and upper ureteral calculi between 4mm and 20mm in size.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription device

David A. Hayman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021775

K02.1775
PG. 1 OF 1.

PREMARKET NOTIFICATION 510(K) SUMMARY

DEC 2 3 2002

Applicant: HealthTronics Surgical Services, Inc.
1841 West Oak Parkway
Marietta, Georgia 30062
Telephone: 770-419-0691
Facsimile: 770-419-9490

Manufacturer: HMT High Medical Technologies, AG
Lengwil, Switzerland

Official Contact: Peter Weiman
Manager of Clinical Programs
HealthTronics Surgical Services, Inc.

The LithoDiamond is indicated for use in patients with renal and upper ureteral calculi between 4m and 20mm in size.

This device is substantially equivalent to the predicate device, the LithoTron (P970019), also manufactured by HMT. The primary difference in the devices is that the LithoDiamond has a new imaging system.

The equivalence argument in the 510(k) was supported by bench data (as outlined in FDA's "Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi." (August 9, 2000)). Detailed shock wave characteristics as well as safety data were presented in the 510(k). An initial report on the imaging system (x-ray component) is also on file at FDA.

Attachment B

HealthTronics™

Storz

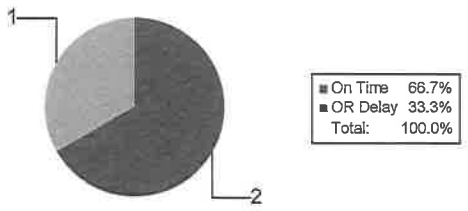
2/2/2015

Q4_2014 Quarterly Review

Trending

	Patients	Stones	Duration (min)	Age
Q4-2014	3	3	55.3	62.7
Q3-2014	7	7	47.6	52.6
Q2-2014	6	6	49.3	56.8
Q1-2014	3	3	53.0	57.3

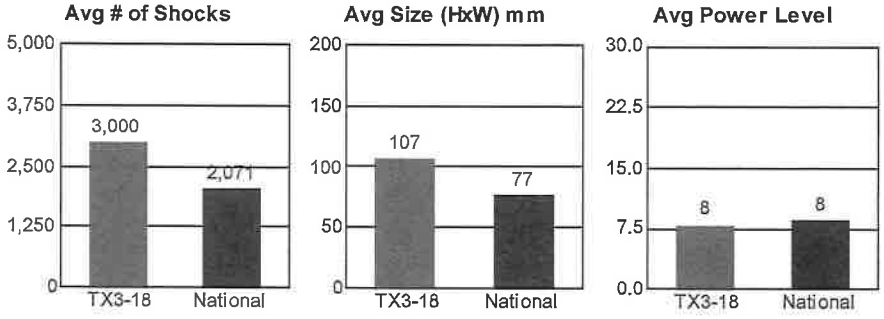
Procedure Status



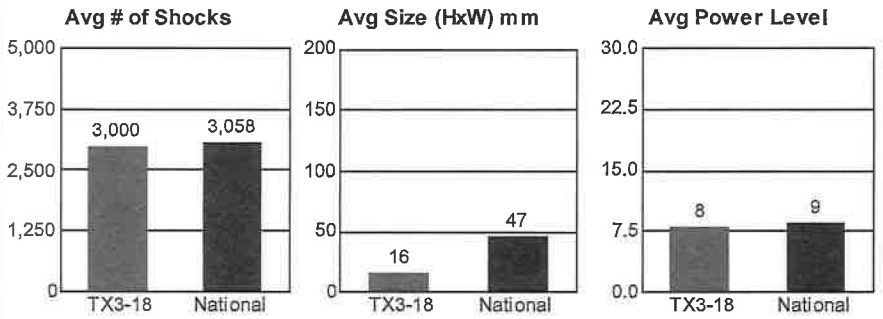
Quality Indicators

Bilateral Procedures:	0/3	0%	10%*
Retreatment Rate:	1/3	33%	10%*
Adjunctive Procedures:	0/3	0%	33%**
Avg Fluoro Time (min):		2:36	5:00*
Stones Under 4mm:	0/3	0%	10%*

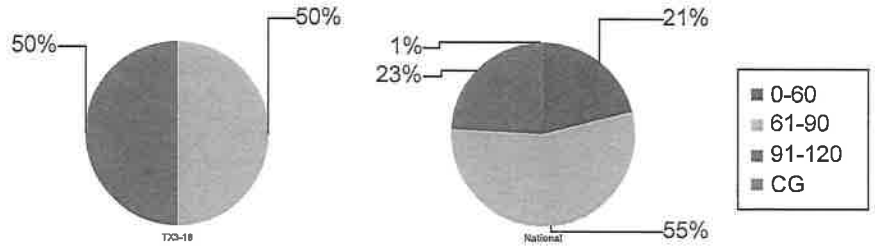
Renal Stones: 2



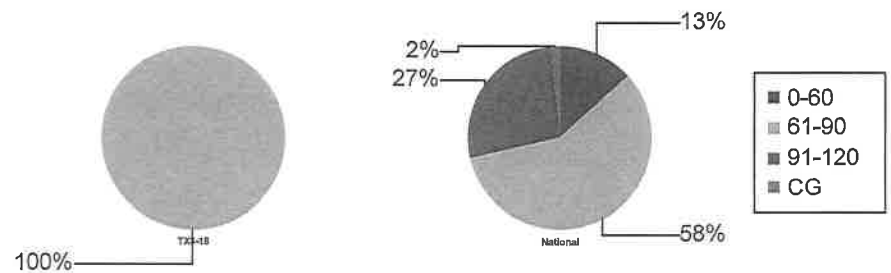
Ureteral Stones: 1



Renal Shocsk Per Minute (%)



Ureteral Shocks Per Minute (%)



**National Numbers based on remaining HTRN data for Machine Type during same period

*Thresholds

Attachment C, I, Need 1 (5)

TRANSFER AGREEMENT

In consideration of the needs of the residents of the area served by both the institutions herein named, this Agreement is entered into as of this the 1st day of April, 2015 ("Effective Date") by and between, LaFollette Medical Center ("Facility") and University Health System, Inc., d/b/a University of Tennessee Memorial Hospital ("UTMH"), each of which herein may be individually referred to as "Party" or collectively as "Parties."

WHEREAS, the Parties are health care facilities serving the health care needs of the residents of their respective service areas; and

WHEREAS, a Party ("Transferring Facility") may, from time to time, require the services of the other Party ("Receiving Facility") to assist with the provision of health care services to the patients served by Transferring Facility;

NOW, THEREFORE, in consideration of the promises herein contained and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

1.0 Under this Agreement, the Receiving Facility will provide treatment and hospitalization for patients of the Transferring Facility when said patients require acute inpatient services, on the conditions set forth in this Agreement. Neither Transferring Facility nor Receiving Facility shall make any decision regarding the transfer or reception of a patient in a discriminatory, arbitrary or capricious manner or in the case of an emergency on the basis of a patient's insurance status or other ability to make payment. However, this shall in no way require either Party to accept nonemergent patients for transfer when the Receiving Facility is not in patient's managed care organization's ("MCO") provider network ("Network") or for whom the Receiving Facility cannot work out other arrangements with MCO, provided however that there is a facility which is in Network that is willing to accept patient.

2.0 This Agreement shall be governed by, and services performed hereunder shall be provided in a manner consistent with, Tennessee and applicable Federal laws and/or regulations, without regard to principles of conflicts of law. This includes, but is not limited to, the provisions of the Emergency Medical Treatment and Active Labor Act ("EMTALA"), 42 USCA §1395dd; Tennessee law regarding patient transfer, TCA 68-11-701-705; EMTALA regulations, 42 CFR 489.24; and Tennessee regulation governing patient transfers, Tenn. Reg. §1200-8-1-.05. This provision shall survive the termination of this Agreement.

3.0 The Transferring Facility assumes responsibility for assuring that the patient is transferred using the appropriate method of transportation and is accompanied by the appropriate personnel and equipment during the transfer. The Transferring Facility assumes responsibility for arrangements for and cost of such transportation, personnel and equipment.

4.0 The Transferring Facility shall assure that the relevant portions of patient's medical record and other relevant information needed to continue the care of the patient are sent with the patient on transport.

5.0 The Receiving Facility agrees to accept the patient for prompt evaluation and, within its capabilities and resources, provide care as indicated after acceptance of patient by a physician at Receiving Facility, contingent upon available space, personnel and resources. The Transferring Facility shall bear no responsibility for the care and treatment provided to any patient after arrival at the Receiving Facility. The Receiving Facility shall bear no responsibility for the care and treatment provided to any patient prior to arrival at the Receiving Facility.

6.0 It is agreed that services rendered by the Receiving Facility or the Transferring Facility shall be charged to the patient and that neither shall be held responsible for payment of services rendered to the patient by the other. The Parties shall cooperate in the provision of the information for each Party to bill for the services provided by them. Each Party will use its best efforts to abide by all policies, regulations and contractual obligations with regard to billing patients and/or third party payors for services it performs.

7.0 Subject to all the transfer policies outlined in this Agreement, Transferring Facility agrees to accept the return transfer of patient when:

7.1 Reasonably requested by Receiving Facility;
7.2 Patient is stable for transport;
7.3 Transfer is acceptable to the patient or, when necessary, acceptable to the patients legal designee;
7.4 A physician at Transferring Facility is willing to assume responsibility for the care and treatment of patient; and
7.5 Transferring Facility has sufficient capabilities and resources to continue patient's course of treatment.

8.0 The Parties agree to promptly notify each other in writing of any incident, occurrence, or claim arising out of or in connection with the transfer or medical treatment of a patient transferred under the Agreement and to cooperate with each other in any investigation of said incident, occurrence, or claim.

9.0 Nothing contained in this Agreement shall be construed or deemed to create a relationship of employer and employee, principal and agent, insured and insurer, partnership, joint venture, or any other relationship other than that of independent parties, contracting with each other solely to carry out the purposes recited in the Agreement.

10.0 Both Parties agree to maintain adequate liability coverage to cover themselves, their employees, contractors and agents from any and all liability arising out of or related to the services provided pursuant to this Agreement including, but not limited to, general and professional liability coverage. However, this provision shall not be construed so as to prohibit the Parties from fulfilling this obligation with various programs of insurance, self-insurance and/or self insured retention. This shall survive the expiration or termination of this Agreement for any reason.

11.0 Either party may terminate this Agreement upon thirty (30) days written notice to the other party. This Agreement shall automatically terminate should either party fail to maintain licensure or certification as provided by law or regulation.

12.0 Both Parties acknowledge that they may have access to confidential protected health information ("PHI") including, but not limited to, patient identifying information. The Parties agree that they (a) will not use or further disclose PHI other than as permitted or required by this Agreement or as permitted or required by law; (b) will protect and safeguard from any oral and written disclosure all confidential information regardless of the type of media on which it is stored (e.g., paper, fiche, etc.) with which it may come into contact; (c) will use appropriate safeguards to prevent use or disclosure of PHI other than as permitted by this Agreement or required by law; (d) will ensure that any subcontractors and agents to which they may provide PHI pursuant to the terms of this Agreement shall agree to all of the same restrictions and conditions to which the Parties are bound; (e) will report to the other Party any unauthorized use or disclosure immediately upon becoming aware of it; (f) will make available PHI in accordance with 45 CFR § 164.524; (g) will make available PHI for amendment and incorporate any amendments to PHI in accordance with 45 CFR § 164.526; (h) will make available the information required to provide an accounting of disclosures in accordance with 45 CFR § 528; (i) will make its internal practices, books and records relating to the use and disclosure of PHI received from, or created or received by one Party on behalf of, the other available to the Secretary of Health and Human Services, governmental officers and agencies and the other Party for purposes of determining compliance with 45 CFR §§ 164.500-534; (j) upon termination of this Agreement, for whatever reason, will return or destroy all PHI, if feasible, received from, or created or received by it on behalf of, the other Party which the other Party maintains in any form, and retain no copies of such information, or if such return or destruction is not feasible, extend the precautions of this Agreement to the information and limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible; and (k) will comply with all applicable laws and regulations, specifically including the private and security standards of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended from time to time. The

Parties agree that any violation of HIPAA with respect to any patient's PHI may result in the termination of this Agreement and/or legal action.

13.0 This Agreement is intended solely for the benefit of UTMH and Facility. All other parties, named or unnamed in this Agreement, shall have no rights or remedies under this Agreement.

14.0 If any provision of this Agreement is held to be illegal or invalid for any reason, such illegality or invalidity shall not affect the remaining portions of this Agreement unless such illegality or invalidity prevents accomplishment of the goals, objectives, or purposes of the Agreement.

15.0 Any waiver of past breach, default, deficient performance or otherwise, even on multiple occasions, shall not be considered as a waiver of any rights or remedies at law or equity in any future circumstance regardless of similarity to past instances.

16.0 Until the expiration of four (4) years after the furnishing of services pursuant to this Agreement or any greater length of time as may be required by applicable federal statute or regulation, the Parties shall make available upon written request from the other Party or the Secretary of the United States Department of Health and Human Services, or upon request of the Comptroller General of the United States or any of their duly authorized representatives, this Agreement and books, documents, and records of that are necessary to certify the nature and extent of costs and services provided under this Agreement.

17.0 The Parties enter into this Agreement with the intent of conducting their relationship in full compliance with applicable state, local and federal law, including the Medicare/Medicaid anti-kickback/Fraud and Abuse provisions. Notwithstanding any unanticipated effect of any provisions herein, neither Party will intentionally conduct itself under the terms of this Agreement in a manner to constitute a violation of said statutes.

18.0 Any requirements imposed under applicable law or regulation as in effect from time to time, shall, where inconsistent with any provision of this Agreement, be controlling and shall govern rights of the Parties hereto. Any such provisions under applicable law or regulation which will supersede or invalidate any provisions hereof shall not affect the validity of this Agreement and the remaining provisions hereof, unless such a change would prevent the accomplishment of the objectives and purposes of this Agreement as set forth herein.

19.0 No revision in or amendment to this Agreement shall be valid unless such revision or amendment is in writing and executed by all Parties hereto.

IN WITNESS WHEREOF, the Parties have entered into this Agreement to be effective as of Effective Date.

FACILITY: LaFollette Medical Center

BY: _____

TITLE: CEO

DATE: 4/14/15

UTMH:
University Health System, Inc.
d/b/a University of Tennessee Memorial Hospital

BY: _____
Gary Thomas

TITLE: Vice President, Compliance and Administration

DATE: March 31, 2015

U. S. Department of Health & Human Services

HRSA Data Warehouse | HRSA.gov

HRSA U. S. Department of Health and Human Services
Health Resources and Services Administration

Enter Keywords SEARCH
HRSA Data Warehouse HRSA.gov

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Find Shortage Areas: MUA/P by State and County

Shortage Designation Home
Find Shortage Areas
HPSA & MUA/P by Address
HPSA by State & County
HPSA Eligible for the Medicare Physician Bonus Payment

Criteria:
State: Tennessee
County: Scott County
ID #: All

Results: 2 records found.

Name	ID#	Type	Score	Designation Date	Update Date
Scott County					
SCOTT SERVICE AREA	03229	MUA	41.50	1978/11/01	1978/11/01
Scott County	1471650183	MUA	57.00	2015/05/14	2015/05/14

NEW SEARCH MODIFY SEARCH CRITERIA

U. S. Department of Health & Human Services

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Find Shortage Areas: MUA/P by State and County

Shortage Designation Home
Find Shortage Areas
HPSA & MUA/P by Address
HPSA by State & County
HPSA Eligible for the Medicare Physician Bonus Payment

Criteria:
State: Tennessee
County: Campbell County
ID #: All

Results: 1 records found.

Name	ID#	Type	Score	Designation Date	Update Date
Campbell County					
CAMPBELL SERVICE AREA	03176	MUA	41.40	1978/11/01	1978/11/01

NEW SEARCH MODIFY SEARCH CRITERIA

U. S. Department of Health & Human Services

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Health Resources and Services Administration

Enter Keywords SEARCH
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Find Shortage Areas: MUA/P by State and County

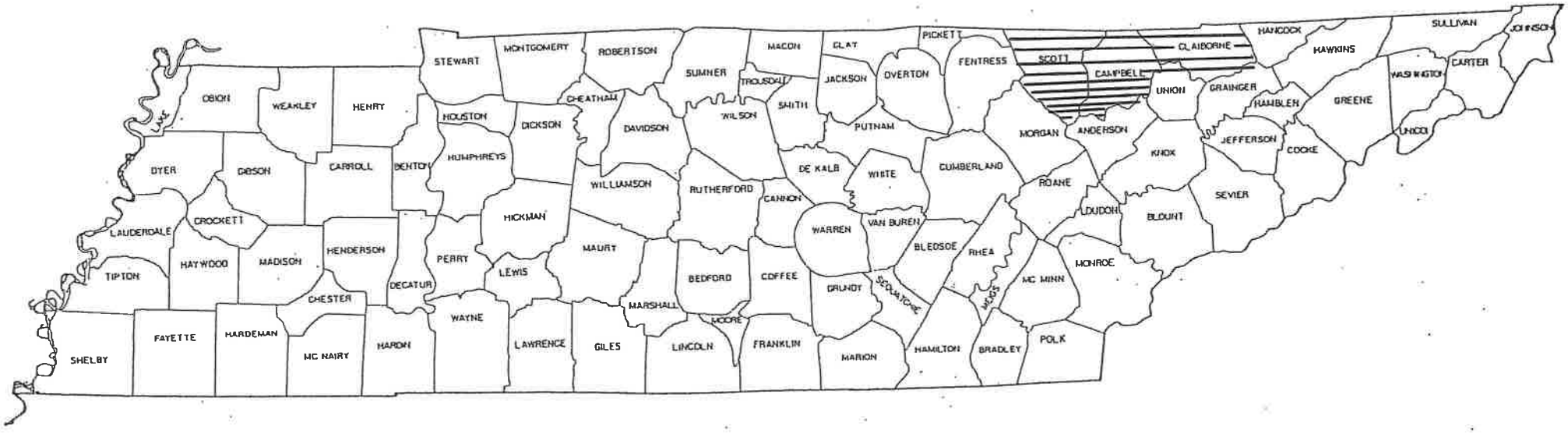
Shortage Designation Home
Find Shortage Areas
HPSA & MUA/P by Address
HPSA by State & County
HPSA Eligible for the Medicare Physician Bonus Payment

Criteria:
State: Tennessee
County: Claiborne County
ID #: All

Results: 1 records found.

Name	ID#	Type	Score	Designation Date	Update Date
Claiborne County					
CLAIBORNE SERVICE AREA	03182	MUA	46.20	1978/11/01	1978/11/01

NEW SEARCH MODIFY SEARCH CRITERIA



Attachment C, I, Need, 3

POPULATION AND DEMOGRAPHICS OF SERVICE AREA				
Variable	**Campbell County**	**Claiborne County**	**Scott County**	**State of Tennessee**
Current Year (2015), Age 65+	7,793	6,000	3,615	1,012,937
Projected Year (2018), Age 65+*	8,122	6,378	3,857	1,102,413
Age 65+, % Change	4.2%	6.3%	6.7%	8.8%
Age 65+, % Total (CY)	18.7%	18.3%	16.5%	15.2%
Age 65+, % Total (PY)	19.1%	19.2%	17.5%	16.1%
CY, Total Population (2015)	41,783	32,765	21,915	6,649,438
PY, Total Population (2018)	42,566	33,280	21,969	6,833,509
Total Pop. % Change	1.9%	1.6%	0.2%	2.8%
TennCare Enrollees (July, 2015)	13,151	9,274	7,964	1,433,687
TennCare Enrollees as a % of Total Population(CY)	31.5%	28.3%	36.3%	21.6%
Median Age (2010 Census)	42	41	38	38
Median Household Income ('09-'13)	$31,943	$33,229	$28,401	$44,298
Population % Below Poverty Level ('09-'13)	23.8%	22.9%	28.3%	17.6

Sources: Population,http://tn.gov/health/article/statistics-con; TennCare enrollment, TennCare Bureau website; Age, TACIR County Profiles website; Income and poverty level, Census Bureau QuickFacts.

CHS

July 31, 2015

Ms. Melanie Hill
Executive Director
Tennessee Health Services and Development Agency
500 Deaderick Street, 9th Floor
Nashville, TN 37243

Re: Funding Support for Certificate of Need Application LaFollette Medical Center-Lithotripsy

Dear Ms. Hill:

CHS / Community Health Systems, Inc., the parent of HMA Campbell County, LLC, d/b/a LaFollette Medical Center, the entity which operates LaFollette Medical Center, has internal funds available for the commitment to the following project, with an approximate project cost of $793,782. CHS/Community Health Systems, Inc. had cash flow from operating activities of $1,615 million in its fiscal year ending 12/31/14, and currently maintains a $1 billion revolving credit facility with excess of $900 million as of 7/31/15 available to fund future cash needs. CHS / Community Health Systems, Inc. is committed to this project and will advance funds as necessary to complete this project.

Should you need anything further, I can be reached at 615-465-7015.

Regards,

Anita H. Passarella
Director Treasury Management, Finance

Cc: Wes Griffith
Chief Financial Officer
LaFollette Medical Center TN

COMMUNITY HEALTH SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME

	Year Ended December 31,		
	2014	2013	2012
	(In millions, except share and per share data)		
Operating revenues (net of contractual allowances and discounts)	$ 21,561	$ 14,853	$ 14,747
Provision for bad debts	2,922	2,034	1,914
Net operating revenues	18,639	12,819	12,833
Operating costs and expenses:			
Salaries and benefits	8,618	6,107	5,992
Supplies	2,862	1,975	1,953
Other operating expenses	4,322	2,818	2,807
Government settlement and related costs	101	102	—
Electronic health records incentive reimbursement	(259)	(162)	(123)
Rent	434	279	264
Depreciation and amortization	1,106	771	714
Amortization of software to be abandoned	75	—	—
Total operating costs and expenses	17,259	11,890	11,607
Income from operations	1,380	929	1,226
Interest expense, net of interest income of $5, $3 and $3 in 2014, 2013 and 2012, respectively	972	613	621
Loss from early extinguishment of debt	73	1	115
Equity in earnings of unconsolidated affiliates	(48)	(43)	(42)
Impairment of long-lived assets	41	12	10
Income from continuing operations before income taxes	342	346	522
Provision for income taxes	82	104	164
Income from continuing operations	260	242	358
Discontinued operations, net of taxes:			
Loss from operations of entities sold or held for sale	(7)	(21)	(12)
Impairment of hospitals sold or held for sale	(50)	(4)	—
Loss from discontinued operations, net of taxes	(57)	(25)	(12)
Net income	203	217	346
Less Net income attributable to noncontrolling interests	111	76	80
Net income attributable to Community Health Systems, Inc. stockholders	$ 92	$ 141	$ 266
Basic earnings (loss) per share attributable to Community Health Systems, Inc. common stockholders(1):			
Continuing operations	$ 1.33	$ 1.80	$ 3.11
Discontinued operations	(0.51)	(0.27)	(0.13)
Net income	$ 0.82	$ 1.52	$ 2.98
Diluted earnings (loss) per share attributable to Community Health Systems, Inc. common stockholders(1):			
Continuing operations	$ 1.32	$ 1.77	$ 3.09
Discontinued operations	(0.51)	(0.27)	(0.13)
Net income	$ 0.82	$ 1.51	$ 2.96
Weighted-average number of shares outstanding			
Basic	111,579,088	92,633,332	89,242,949
Diluted	112,549,320	93,815,013	89,806,937

(1) Total per share amounts may not add due to rounding.

See notes to the consolidated financial statements.

COMMUNITY HEALTH SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

	Year Ended December 31,		
	2014	2013	2012
	(In millions)		
Net income	$ 203	$ 217	$ 346
Other comprehensive income (loss), net of income taxes:			
Net change in fair value of interest rate swaps, net of tax of $7, $34 and $26 for the years ended December 31, 2014, 2013 and 2012, respectively	13	60	46
Net change in fair value of available-for-sale securities, net of tax	—	2	3
Amortization and recognition of unrecognized pension cost components, net of tax (benefit) of $(9), $9 and $(3) for the years ended December 31, 2014, 2013 and 2012, respectively	(9)	16	(10)
Other comprehensive income	4	78	39
Comprehensive income	207	295	385
Less: Comprehensive income attributable to noncontrolling interests	111	76	80
Comprehensive income attributable to Community Health Systems, Inc. stockholders	$ 96	$ 219	$ 305

See notes to the consolidated financial statements.

COMMUNITY HEALTH SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2014	2013
	(In millions, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 509	$ 373
Patient accounts receivable, net of allowance for doubtful accounts of $3,504 and $2,438 at December 31, 2014 and 2013, respectively	3,409	2,323
Supplies	557	371
Prepaid income taxes	30	107
Deferred income taxes	341	101
Prepaid expenses and taxes	192	127
Other current assets (including assets of hospitals held for sale of $38 and $40 at December 31, 2014 and 2013, respectively)	528	345
Total current assets	5,566	3,747
Property and equipment:		
Land and improvements	946	623
Buildings and improvements	8,791	6,225
Equipment and fixtures	4,527	3,614
Property and equipment, gross	14,264	10,462
Less accumulated depreciation and amortization	(4,095)	(3,411)
Property and equipment, net	10,169	7,051
Goodwill	8,951	4,424
Other assets, net of accumulated amortization of $827 and $535 at December 31, 2014 and 2013 respectively (including assets of hospitals held for sale of $90 and $94 at December 31, 2014 and 2013, respectively)	2,735	1,895
Total assets	$27,421	$ 17,117
LIABILITIES AND EQUITY		
Current liabilities:		
Current maturities of long-term debt	$ 235	$ 167
Accounts payable	1,293	949
Deferred income taxes	23	3
Accrued liabilities:		
Employee compensation	955	690
Interest	227	112
Other (including liabilities of hospitals held for sale of $10 and $24 at December 31, 2014 and 2013, respectively)	856	537
Total current liabilities	3,589	2,458
Long-term debt	16,681	9,286
Deferred income taxes	845	906
Other long-term liabilities	1,692	977
Total liabilities	22,807	13,627
Redeemable noncontrolling interests in equity of consolidated subsidiaries	531	358
Commitments and contingencies (Note 16)		
EQUITY		
Community Health Systems, Inc. stockholders' equity:		
Preferred stock, $.01 par value per share, 100,000,000 shares authorized; none issued	—	—
Common stock, $.01 par value per share, 300,000,000 shares authorized; 117,701,087 shares issued and 116,725,538 shares outstanding at December 31, 2014, and 95,987,032 shares issued and 95,011,483 shares outstanding at December 31, 2013	1	1
Additional paid-in capital	2,095	1,256
Treasury stock, at cost, 975,549 shares at December 31, 2014 and 2013	(7)	(7)
Accumulated other comprehensive loss	(63)	(67)
Retained earnings	1,977	1,885
Total Community Health Systems, Inc. stockholders' equity	4,003	3,068
Noncontrolling interests in equity of consolidated subsidiaries	80	64
Total equity	4,083	3,132
Total liabilities and equity	$27,421	$ 17,117

See notes to the consolidated financial statements.

Campbell County HMA, LLC

Organization ID: 3915

923 East Central AvenueLa Follette, TN 37766

Accreditation Activity - 45-day Evidence of Standards Compliance Form

Due Date: 8/10/2014

HAP	**Standard EC.02.05.07**	**The hospital inspects, tests, and maintains emergency power systems. Note: This standard does not require hospitals to have the types of emergency power equipment discussed below. However, if these types of equipment exist within the building, then the following maintenance, testing, and inspection requirements apply.**

Findings: EP 5 §482.41(c)(2) - (A-0724) - (2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. This Standard is NOT MET as evidenced by: Observed in Document Review at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the document Review on 6/17/14, there was not a 30% load test run on the main hospital generator for the month of July 2013. While the monthly test was completed it did not reach the required 30% of the nameplate of the generator (200amps of 600amps) Observed in Document Review at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the document Review on 6/17/14, there was not a 30% load test run on the main hospital generator for the month of October 2013. While the monthly test was completed it did not reach the required 30% of the nameplate of the generator (200 amps of 600 amps) EP 6 §482.41(c)(2) - (A-0724) - (2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. This Standard is NOT MET as evidenced by: Observed in Document Review at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the document Review on 6/17/14, the hospital performed each of it's three transfer tests each month. However they did not record the transfer times as required. They had never done this so none of their testing records showed any transfer times.

Elements of Performance:

5. The monthly tests for diesel-powered emergency generators are conducted with a dynamic load that is at least 30% of the nameplate rating of the generator or meets the manufacturer's recommended prime movers' exhaust gas temperature. If the hospital does not meet either the 30% of nameplate rating or the recommended exhaust gas temperature during any test in EC.02.05.07, EP 4, then it must test the emergency generator once every 12 months using supplemental (dynamic or static) loads of 25% of nameplate rating for 30 minutes, followed by 50% of nameplate rating for 30 minutes, followed by 75% of nameplate rating for 60 minutes, for a total of 2 continuous hours. Note: Tests for non–diesel-powered generators need only be conducted with available load.

Scoring Category: A

Corrective Action Taken:
WHO:

The Plant Operations Manager is ultimately responsible for the corrective action and for overall and ongoing

compliance.

WHAT:

The "EC.02.05.07.1-10 - Emergency Power Systems" policy and forms has replaced our old policy "Conditions for Load Testing Emergency Generators" and forms effective 08/01/2014. The "Emergency Power Systems" policy was taken before the Safety Committee and approved on 07/31/2014. Monthly generator checks have been added to the PM system. Engineering personnel will be educated on the new policy and forms effective immediately and this policy and forms will be gone over in new employee orientation.

WHEN:

We implemented the new policy "EC.02.05.07.1-10 - Emergency Power Systems" and forms,effective 08/01/2014, this was approved by the Safety Committee on 07/31/2014. Engineering personnel will be educated on the new policy and forms by 08/08/14 via unit meeting. A copy of the new policy and forms were given to the Plant Operations Manager review with staff not present during the unit meeting. The first generator test under policy "EC.02.05.07.1-10 - Emergency Power Systems" according to the new policy/forms was successfully completed on 08/04/14.

HOW:

The Plant Operations Manager will report monthly generator load tests and annual load bank tests to the Safety Committee for one year. The monthly generator checks have been added to the PM system.

HAP **Standard EC.02.05.09** **The hospital inspects, tests, and maintains medical gas and vacuum systems. Note: This standard does not require hospitals to have the medical gas and vacuum systems discussed below. However, if a hospital has these types of systems, then the following inspection, testing, and maintenance requirements apply.**

Findings: EP 1 Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. OBSERVED during the building tour on 6/18/2014, the organization could not produce any records to show that the medical gas master alarm panel in the emergency department had been tested since 2011. The only document available to the surveyor was a report from the bulk oxygen supplier stating that ALL ALARMS HAD BEEN TESTED. This document had no inventory attached to it, no description of a testing interval or the testing procedure. EP 3 Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. OBSERVED during the building tour on 6/17/14, the bulk oxygen storage tank had a source valve that was not labeled as a source valve nor did it indicate what the valve served.

Elements of Performance:

1. In time frames defined by the hospital, the hospital inspects, tests, and maintains critical components of piped medical gas systems, including master signal panels, area alarms, automatic pressure switches, shutoff valves, flexible connectors, and outlets. These activities are documented. (See also EC.02.05.01, EP 3)

Scoring Category: A

Corrective Action Taken:

WHO:

The Plant Operations Manager and Director of Respiratory Care Services are ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

The policy "EC.02.05.09.1-3 - Piped Medical Gas and Vacuum Systems" was developed, approved, and implemented on 07/31/2014 by the Safety Committee. The education of all engineering and respiratory care personnel began immediately via unit meetings. As per the policy, annual testing and inspection of piped medical gases and vacuum systems will be completed. The annual inspection report will be reported to the Safety Committee.

WHEN:

The "EC.02.05.09.1-3 - Piped Medical Gas and Vacuum Systems" policy was developed and approved on 07/31/2014 by the Safety Committee. The education of engineering and respiratory care personnel was done by the Plant Operations Manager and Director of Respiratory Services via unit meetings and was completed on 08/08/14. The vendor was contacted to request the first annual inspection of the piped medical gas and vacuum system on 07/30/14. The annual inspection of piped medical gas and vacuum systems were completed on 08/08/14.

HOW:

The Plant Operations Manager will maintain the yearly report from the vendor and this will be reported yearly through the Safety Committee meeting. Any deficiencies detailed in the report will be completed immediately and any re-testing will be conducted after corrections are made.

HAP Standard MM.05.01.01 A pharmacist reviews the appropriateness of all medication orders for medications to be dispensed in the hospital.

Findings: EP 8 Observed in Individual Tracer at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. Observed po and IV PRN orders for Zofran without an indication which to formulation to give first. Observed in Tracer Activities at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. Observed po and IV PRN orders for lorazepam without an indication which to give first

Elements of Performance:

8. All medication orders are reviewed for the following: Therapeutic duplication.

Scoring Category: C

Corrective Action Taken:

WHO:

The Director of Pharmacy is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

The "Safe Administration of Medications and Reducing the Risk of Over Medicating by PRN Medications in same Therapeutic Classes" policy was reviewed and revised on 07/31/14. Physician Order sets were also reviewed and revised to assure there were no therapeutic duplication(s) 07/31/14. The policy was approved by the Pharmacy and Therapeutic Committee on 07/31/14, and Medical Executive Committee on 08/06/14. The education of pharmacy staff was completed via unit meeting on 07/31/14. The education of physicians was completed 08/08/14 during Medical Executive Committee and Medical Staff meeting by the Director of Pharmacy. New physicians will be educated during initial facility or orientation.

WHEN:

The "Safe Administration of Medications and Reducing the Risk of Over Medicating by PRN Medications in same Therapeutic Classes" policy was reviewed and revised on 07/31/14. Physician order sets were also reviewed and revised to assure there were no therapeutic duplication(s) on 07/31/14. The policy and physician

order set(s) revisions were approved by the Pharmacy and Therapeutic Committee on 07/31/14, and Medical Executive Committee on 08/06/14. The education of pharmacy staff was completed via unit meeting on 07/31/14. The education of physicians was completed 08/08/14 during Medical Executive Committee and Medical Staff meeting by the Director of Pharmacy. New physicians will be educated during initial facility or orientation.

HOW:

The Director of Pharmacy will audit 30 charts per month for four months with a compliance rate of 90% or better.

Evaluation Method: 1. Sample size: Based on Average Daily Census of 37, 30 records will be selected using random selection. 2. The records will be randomly selected by running a list of discharged patient, then selecting every 3rd record until 30 charts are identified. 3. This will be monitored monthly for four consecutive months. 4. The denominator equals the total number of orders reviewed that contain potential or actual therapeutic duplication. 5. The numerator equals the number of orders where medications are correctly ordered without therapeutic duplication. 6. The data will be reported monthly to the Pharmacy and Therapeutics's Committee by the Director of Pharmacy, and forwarded to the Quality Department.

Measure of Success Goal (%): 90

HAP Standard MS.03.01.01 **The organized medical staff oversees the quality of patient care, treatment, and services provided by practitioners privileged through the medical staff process.**

Findings: EP 2 §482.12(a)(5) - (A-0049) - [The governing body must:] (5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients; This Standard is NOT MET as evidenced by: Observed in Competency Session at LaFollette Med Ctr Jacksboro Clinic (3170 Appalachian Highway, Suite 5, Jacksboro, TN) site for the Hospital deemed service. observed LIPs (nurse practitioner and physician assistant) performing duties such as physical assessments ,interpretations, histories, physicals, and exercising prescriptive authority in out-patient clinics. No privileges were granted however, to practice as an LIP in either instance. Interviews with human resources states that they did not believe credentialing was required as these LIPs do not practice at the physical location of the hospital. Both clinics were surveyed under HAP standards and operate under the same CCN and same HCO as the main hospital.

Elements of Performance:

2. Practitioners practice only within the scope of their privileges as determined through mechanisms defined by the organized medical staff.

Scoring Category: A

Corrective Action Taken:

WHO:

The Regional Medical Staff Coordinator is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

The completed applications for the 2 off-site allied health providers were forwarded to the Regional Medical Staff Coordinator on July 21, 2014 for the Physician Assistant and on July 25, 2014 for the Nurse Practitioner to

start the credentialing process. Our facility is now working with Team Physician Services, Physician Management Entity and Director of Operations & Finance/Tennessee Division, Physician Network with all new physicians and/or extended providers with credentialing forwarded to the medical staff coordinator. All Physician Assistants and Nurse Practitioners are required to be credentialed by the Governing Board prior to performing duties.

WHEN:

Applications for the Physician Assistant and Nurse Practitioner were completed on July 25, 2014.

HOW:

All Physician Assistants and Nurse Practitioners will be required to credentialed initially; and re-credentialed every 2 years.

HAP Standard NPSG.03.06.01 Maintain and communicate accurate patient medication information.

Findings: EP 4 Observed in Individual Tracer at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. The medical record for a patient who had undergone a ophthalmic surgical procedure documented three medications identified at time of admission on the medication reconciliation list. The family physician's history listed six medications in current use. At the time of discharge only three medications were mentioned in the discharge instructions and the record did not document when the next doses were to be taken. Nurses indicated that they had discussed the next doses with the patient at the time of discharge, but did not retain a copy of the information that they provided to the patient. Observed in Individual Tracer at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. The medical record of a patient was reviewed on the day of discharge from the hospital. Two of six medications listed on the admission medication reconciliation list were not referred to at the time of discharge regarding whether or not they were to be taken or when they were to be taken. Nurses indicated that they had discussed four of the six, the ones that they were aware of, but had not documented the discussion.

Elements of Performance:

4. Provide the patient (or family as needed) with written information on the medications the patient should be taking when he or she is discharged from the hospital or at the end of an outpatient encounter (for example, name, dose, route, frequency, purpose). Note: When the only additional medications prescribed are for a short duration, the medication information the hospital provides may include only those medications. For more information about communications to other providers of care when the patient is discharged or transferred, refer to Standard PC.04.02.01.

Scoring Category: C

Corrective Action Taken:

WHO:

The Director of Pharmacy is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

The "Medication Reconciliation on Patient Admissions, Transfers Across the Continuum of Care upon Discharge, and Documentation Guidelines For" policy was reviewed and revised on 07/31/14 by the Pharmacy and Therapeutics Committee to include comparison of the medication reconciliation form to the history and physical in the outpatient surgery setting. Education to surgical staff was completed on 08/08/14 via staff meeting and a copy of the new policy given to the Manager of Surgical Services to review with staff not present

at meetings.There were no changes made to the Medication Reconciliation Form.

WHEN:

The "Medication Reconciliation on Patient Admissions, Transfers Across the Continuum of Care upon Discharge, and Documentation Guidelines For" policy was reviewed and revised on 07/31/14 by the Pharmacy and Therapeutics Committee to include comparison of the medication reconciliation form to the history and physical in the outpatient surgery setting. Education to surgical staff was completed on 08/08/14 via staff meeting and a copy of the new policy given to the Manager of Surgical Services to review with staff not present at meetings.There were no changes made to the Medication Reconciliation Form.

HOW:

The Director of Pharmacy will audit 30 charts per month for four months with a compliance rate of 90% or better.

Evaluation Method: 1. Sample size: Based on Average Daily Census of 37, 30 records will be selected using random selection. 2. The records will be randomly selected by running a list of discharged patient, then selecting every 3rd record until 30 charts are identified. 3. This will be monitored monthly for four consecutive months. 4. The denominator equals the total number of opportunities in the chart, if medication reconciliation was done 4 times in a chart, that chart has four (4) opportunities. 5. The numerator equals the number of performance(s) done correctly, if the chart had four (4) medication reconciliations in a chart, all four (4) were done correctly. 6. The data will be reported monthly to the Pharmacy and Therapeutics's Committee by the Director of Pharmacy.

Measure of Success Goal (%): 90

HAP Standard RI.01.03.01 The hospital honors the patient's right to give or withhold informed consent.

Findings: EP 11 §482.13(b)(2) - (A-0131) - (2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. This Standard is NOT MET as evidenced by: Observed in Individual Tracer at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. The hospital's informed consent policy did not include a requirement that there be a discussion regarding the risks related to not receiving the proposed care, treatment and services. Three cases of surgical care were reviewed containing detailed descriptions of the risks, benefits and alternatives of the proposed procedure, but not the risk of not performing the procedure. These included cases of carotid endarterectomy, cataract removal, and peripheral arterial bypass.

Elements of Performance:

11. The informed consent process includes a discussion about reasonable alternatives to the patient's proposed care, treatment, and services. The discussion encompasses risks, benefits, and side effects related to the alternatives and the risks related to not receiving the proposed care, treatment, and services.

Scoring Category: A

Corrective Action Taken:

WHO:

The Quality Manager is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

The informed consent "Surgery/Special Procedure/Anesthesia" was reviewed and revised on 07/25/14. The "Informed consent" policy was reviewed and revised on 07/25/14. The wording on the consent was changed to "The nature, purpose, benefits, risks, side effects, likelihood of achieving goals, potential problems that might occur during recuperation, risks for not receiving the proposed care, treatment, and services, and alternatives of the proposed operation/procedure, including the risks, benefits, and side effects related to the alternatives have been fully explained to me by my physician including, but not limited to...". The consent/policy was approved by the Operative Committee on 07/28/14, and Medical Executive Committee on 08/06/14. The education of physicians was completed on 08/08/14 through Medical Executive Committee, Medical Staff Meeting and Operative Case Committee. The staff was completed on 08/08/14 via unit meetings and a copy of the new policy and consent given to Medical Surgical/ICU/ED/Surgery managers to review with staff not present in meetings.

WHEN:

The informed consent "Surgery/Special Procedure/Anesthesia" was approved by the Operative Committee on 07/28/14 and Medical Executive Committee on 08/06/14. The education of physicians was completed on 08/08/14 through Medical Executive Committee, Medical Staff Meeting and Operative Case Committee. The staff was completed on 08/08/14 via unit meetings and a copy of the new policy and consent given to Medical Surgical/ICU/ED/Surgery managers to review with staff not present in meetings.

HOW:

The Quality Manager will monitor compliance: 1. Sample size: Based on Average Daily Census of 37, 30 records will be selected using random selection. 2. The records will be randomly selected by running a list of discharged patient, then selecting every 3rd record until 30 charts are identified. 3. This will be monitored monthly for four consecutive months. 4. The denominator equals the total number of operative permits reviewed. 5. The numerator equals the number of records in which the operative permits were completed correctly. 6. The data will be reported quarterly to the Operative Committee and PI Committee with a compliance of 90% or better by the Director of Quality.

Campbell County HMA, LLC

Organization ID: 3915

923 East Central AvenueLa Follette, TN 37766

Accreditation Activity - 45-day Evidence of Standards Compliance Form

Due Date: 8/10/2014

HAP	**Standard EC.02.05.07**	**The hospital inspects, tests, and maintains emergency power systems. Note: This standard does not require hospitals to have the types of emergency power equipment discussed below. However, if these types of equipment exist within the building, then the following maintenance, testing, and inspection requirements apply.**

Findings: EP 5 §482.41(c)(2) - (A-0724) - (2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. This Standard is NOT MET as evidenced by: Observed in Document Review at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the document Review on 6/17/14, there was not a 30% load test run on the main hospital generator for the month of July 2013. While the monthly test was completed it did not reach the required 30% of the nameplate of the generator (200amps of 600amps) Observed in Document Review at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the document Review on 6/17/14, there was not a 30% load test run on the main hospital generator for the month of October 2013. While the monthly test was completed it did not reach the required 30% of the nameplate of the generator (200 amps of 600 amps) EP 6 §482.41(c)(2) - (A-0724) - (2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. This Standard is NOT MET as evidenced by: Observed in Document Review at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the document Review on 6/17/14, the hospital performed each of it's three transfer tests each month. However they did not record the transfer times as required. They had never done this so none of their testing records showed any transfer times.

Elements of Performance:

5. The monthly tests for diesel-powered emergency generators are conducted with a dynamic load that is at least 30% of the nameplate rating of the generator or meets the manufacturer's recommended prime movers' exhaust gas temperature. If the hospital does not meet either the 30% of nameplate rating or the recommended exhaust gas temperature during any test in EC.02.05.07, EP 4, then it must test the emergency generator once every 12 months using supplemental (dynamic or static) loads of 25% of nameplate rating for 30 minutes, followed by 50% of nameplate rating for 30 minutes, followed by 75% of nameplate rating for 60 minutes, for a total of 2 continuous hours. Note: Tests for non–diesel-powered generators need only be conducted with available load.

Scoring Category: A

Corrective Action Taken:
WHO:

The Plant Operations Manager is ultimately responsible for the corrective action and for overall and ongoing

compliance.

WHAT:

The "EC.02.05.07.1-10 - Emergency Power Systems" policy and forms has replaced our old policy "Conditions for Load Testing Emergency Generators" and forms effective 08/01/2014. The "Emergency Power Systems" policy was taken before the Safety Committee and approved on 07/31/2014. Monthly generator checks have been added to the PM system. Engineering personnel will be educated on the new policy and forms effective immediately and this policy and forms will be gone over in new employee orientation.

WHEN:

We implemented the new policy "EC.02.05.07.1-10 - Emergency Power Systems" and forms,effective 08/01/2014, this was approved by the Safety Committee on 07/31/2014. Engineering personnel will be educated on the new policy and forms by 08/08/14 via unit meeting. A copy of the new policy and forms were given to the Plant Operations Manager review with staff not present during the unit meeting. The first generator test under policy "EC.02.05.07.1-10 - Emergency Power Systems" according to the new policy/forms was successfully completed on 08/04/14.

HOW:

The Plant Operations Manager will report monthly generator load tests and annual load bank tests to the Safety Committee for one year. The monthly generator checks have been added to the PM system.

HAP	**Standard EC.02.05.09**	**The hospital inspects, tests, and maintains medical gas and vacuum systems. Note: This standard does not require hospitals to have the medical gas and vacuum systems discussed below. However, if a hospital has these types of systems, then the following inspection, testing, and maintenance requirements apply.**

Findings: EP 1 Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. OBSERVED during the building tour on 6/18/2014, the organization could not produce any records to show that the medical gas master alarm panel in the emergency department had been tested since 2011. The only document available to the surveyor was a report from the bulk oxygen supplier stating that ALL ALARMS HAD BEEN TESTED. This document had no inventory attached to it, no description of a testing interval or the testing procedure. EP 3 Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. OBSERVED during the building tour on 6/17/14, the bulk oxygen storage tank had a source valve that was not labeled as a source valve nor did it indicate what the valve served.

Elements of Performance:

1. In time frames defined by the hospital, the hospital inspects, tests, and maintains critical components of piped medical gas systems, including master signal panels, area alarms, automatic pressure switches, shutoff valves, flexible connectors, and outlets. These activities are documented. (See also EC.02.05.01, EP 3)

Scoring Category: A

Corrective Action Taken:

WHO:

The Plant Operations Manager and Director of Respiratory Care Services are ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

The policy "EC.02.05.09.1-3 - Piped Medical Gas and Vacuum Systems" was developed, approved, and implemented on 07/31/2014 by the Safety Committee. The education of all engineering and respiratory care personnel began immediately via unit meetings. As per the policy, annual testing and inspection of piped medical gases and vacuum systems will be completed. The annual inspection report will be reported to the Safety Committee.

WHEN:

The "EC.02.05.09.1-3 - Piped Medical Gas and Vacuum Systems" policy was developed and approved on 07/31/2014 by the Safety Committee. The education of engineering and respiratory care personnel was done by the Plant Operations Manager and Director of Respiratory Services via unit meetings and was completed on 08/08/14. The vendor was contacted to request the first annual inspection of the piped medical gas and vacuum system on 07/30/14. The annual inspection of piped medical gas and vacuum systems were completed on 08/08/14.

HOW:

The Plant Operations Manager will maintain the yearly report from the vendor and this will be reported yearly through the Safety Committee meeting. Any deficiencies detailed in the report will be completed immediately and any re-testing will be conducted after corrections are made.

HAP Standard MM.05.01.01 A pharmacist reviews the appropriateness of all medication orders for medications to be dispensed in the hospital.

Findings: EP 8 Observed in Individual Tracer at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. Observed po and IV PRN orders for Zofran without an indication which to formulation to give first. Observed in Tracer Activities at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. Observed po and IV PRN orders for lorazepam without an indication which to give first

Elements of Performance:

8. All medication orders are reviewed for the following: Therapeutic duplication.

Scoring Category: C

Corrective Action Taken:

WHO:

The Director of Pharmacy is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

The "Safe Administration of Medications and Reducing the Risk of Over Medicating by PRN Medications in same Therapeutic Classes" policy was reviewed and revised on 07/31/14. Physician Order sets were also reviewed and revised to assure there were no therapeutic duplication(s) 07/31/14. The policy was approved by the Pharmacy and Therapeutic Committee on 07/31/14, and Medical Executive Committee on 08/06/14. The education of pharmacy staff was completed via unit meeting on 07/31/14. The education of physicians was completed 08/08/14 during Medical Executive Committee and Medical Staff meeting by the Director of Pharmacy. New physicians will be educated during initial facility or orientation.

WHEN:

The "Safe Administration of Medications and Reducing the Risk of Over Medicating by PRN Medications in same Therapeutic Classes" policy was reviewed and revised on 07/31/14. Physician order sets were also reviewed and revised to assure there were no therapeutic duplication(s) on 07/31/14. The policy and physician

order set(s) revisions were approved by the Pharmacy and Therapeutic Committee on 07/31/14, and Medical Executive Committee on 08/06/14. The education of pharmacy staff was completed via unit meeting on 07/31/14. The education of physicians was completed 08/08/14 during Medical Executive Committee and Medical Staff meeting by the Director of Pharmacy. New physicians will be educated during initial facility or orientation.

HOW:

The Director of Pharmacy will audit 30 charts per month for four months with a compliance rate of 90% or better.

Evaluation Method: 1. Sample size: Based on Average Daily Census of 37, 30 records will be selected using random selection. 2. The records will be randomly selected by running a list of discharged patient, then selecting every 3rd record until 30 charts are identified. 3. This will be monitored monthly for four consecutive months. 4. The denominator equals the total number of orders reviewed that contain potential or actual therapeutic duplication. 5. The numerator equals the number of orders where medications are correctly ordered without therapeutic duplication. 6. The data will be reported monthly to the Pharmacy and Therapeutics's Committee by the Director of Pharmacy, and forwarded to the Quality Department.

Measure of Success Goal (%): 90

HAP Standard MS.03.01.01 **The organized medical staff oversees the quality of patient care, treatment, and services provided by practitioners privileged through the medical staff process.**

Findings: EP 2 §482.12(a)(5) - (A-0049) - [The governing body must:] (5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients; This Standard is NOT MET as evidenced by: Observed in Competency Session at LaFollette Med Ctr Jacksboro Clinic (3170 Appalachian Highway, Suite 5, Jacksboro, TN) site for the Hospital deemed service. observed LIPs (nurse practitioner and physician assistant) performing duties such as physical assessments ,interpretations, histories, physicals, and exercising prescriptive authority in out-patient clinics. No privileges were granted however, to practice as an LIP in either instance. Interviews with human resources states that they did not believe credentialing was required as these LIPs do not practice at the physical location of the hospital. Both clinics were surveyed under HAP standards and operate under the same CCN and same HCO as the main hospital.

Elements of Performance:

2. Practitioners practice only within the scope of their privileges as determined through mechanisms defined by the organized medical staff.

Scoring Category: A

Corrective Action Taken:

WHO:

The Regional Medical Staff Coordinator is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

The completed applications for the 2 off-site allied health providers were forwarded to the Regional Medical Staff Coordinator on July 21, 2014 for the Physician Assistant and on July 25, 2014 for the Nurse Practitioner to

start the credentialing process. Our facility is now working with Team Physician Services, Physician Management Entity and Director of Operations & Finance/Tennessee Division, Physician Network with all new physicians and/or extended providers with credentialing forwarded to the medical staff coordinator. All Physician Assistants and Nurse Practitioners are required to be credentialed by the Governing Board prior to performing duties.

WHEN:

Applications for the Physician Assistant and Nurse Practitioner were completed on July 25, 2014.

HOW:

All Physician Assistants and Nurse Practitioners will be required to credentialed initially; and re-credentialed every 2 years.

HAP Standard NPSG.03.06.01 Maintain and communicate accurate patient medication information.

Findings: EP 4 Observed in Individual Tracer at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. The medical record for a patient who had undergone a ophthalmic surgical procedure documented three medications identified at time of admission on the medication reconciliation list. The family physician's history listed six medications in current use. At the time of discharge only three medications were mentioned in the discharge instructions and the record did not document when the next doses were to be taken. Nurses indicated that they had discussed the next doses with the patient at the time of discharge, but did not retain a copy of the information that they provided to the patient. Observed in Individual Tracer at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. The medical record of a patient was reviewed on the day of discharge from the hospital. Two of six medications listed on the admission medication reconciliation list were not referred to at the time of discharge regarding whether or not they were to be taken or when they were to be taken. Nurses indicated that they had discussed four of the six, the ones that they were aware of, but had not documented the discussion.

Elements of Performance:

4. Provide the patient (or family as needed) with written information on the medications the patient should be taking when he or she is discharged from the hospital or at the end of an outpatient encounter (for example, name, dose, route, frequency, purpose). Note: When the only additional medications prescribed are for a short duration, the medication information the hospital provides may include only those medications. For more information about communications to other providers of care when the patient is discharged or transferred, refer to Standard PC.04.02.01.

Scoring Category: C

Corrective Action Taken:

WHO:

The Director of Pharmacy is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

The "Medication Reconciliation on Patient Admissions, Transfers Across the Continuum of Care upon Discharge, and Documentation Guidelines For" policy was reviewed and revised on 07/31/14 by the Pharmacy and Therapeutics Committee to include comparison of the medication reconciliation form to the history and physical in the outpatient surgery setting. Education to surgical staff was completed on 08/08/14 via staff meeting and a copy of the new policy given to the Manager of Surgical Services to review with staff not present

at meetings.There were no changes made to the Medication Reconciliation Form.

WHEN:

The "Medication Reconciliation on Patient Admissions, Transfers Across the Continuum of Care upon Discharge, and Documentation Guidelines For" policy was reviewed and revised on 07/31/14 by the Pharmacy and Therapeutics Committee to include comparison of the medication reconciliation form to the history and physical in the outpatient surgery setting. Education to surgical staff was completed on 08/08/14 via staff meeting and a copy of the new policy given to the Manager of Surgical Services to review with staff not present at meetings.There were no changes made to the Medication Reconciliation Form.

HOW:

The Director of Pharmacy will audit 30 charts per month for four months with a compliance rate of 90% or better.

Evaluation Method: 1. Sample size: Based on Average Daily Census of 37, 30 records will be selected using random selection. 2. The records will be randomly selected by running a list of discharged patient, then selecting every 3rd record until 30 charts are identified. 3. This will be monitored monthly for four consecutive months. 4. The denominator equals the total number of opportunities in the chart, if medication reconciliation was done 4 times in a chart, that chart has four (4) opportunities. 5. The numerator equals the number of performance(s) done correctly, if the chart had four (4) medication reconciliations in a chart, all four (4) were done correctly. 6. The data will be reported monthly to the Pharmacy and Therapeutics's Committee by the Director of Pharmacy.

Measure of Success Goal (%): 90

HAP Standard RI.01.03.01 The hospital honors the patient's right to give or withhold informed consent.

Findings: EP 11 §482.13(b)(2) - (A-0131) - (2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. This Standard is NOT MET as evidenced by: Observed in Individual Tracer at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. The hospital's informed consent policy did not include a requirement that there be a discussion regarding the risks related to not receiving the proposed care, treatment and services. Three cases of surgical care were reviewed containing detailed descriptions of the risks, benefits and alternatives of the proposed procedure, but not the risk of not performing the procedure. These included cases of carotid endarterectomy, cataract removal, and peripheral arterial bypass.

Elements of Performance:

11. The informed consent process includes a discussion about reasonable alternatives to the patient's proposed care, treatment, and services. The discussion encompasses risks, benefits, and side effects related to the alternatives and the risks related to not receiving the proposed care, treatment, and services.

Scoring Category: A

Corrective Action Taken:

WHO:

The Quality Manager is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

The informed consent "Surgery/Special Procedure/Anesthesia" was reviewed and revised on 07/25/14. The "Informed consent" policy was reviewed and revised on 07/25/14. The wording on the consent was changed to "The nature, purpose, benefits, risks, side effects, likelihood of achieving goals, potential problems that might occur during recuperation, risks for not receiving the proposed care, treatment, and services, and alternatives of the proposed operation/procedure, including the risks, benefits, and side effects related to the alternatives have been fully explained to me by my physician including, but not limited to...". The consent/policy was approved by the Operative Committee on 07/28/14, and Medical Executive Committee on 08/06/14. The education of physicians was completed on 08/08/14 through Medical Executive Committee, Medical Staff Meeting and Operative Case Committee. The staff was completed on 08/08/14 via unit meetings and a copy of the new policy and consent given to Medical Surgical/ICU/ED/Surgery managers to review with staff not present in meetings.

WHEN:

The informed consent "Surgery/Special Procedure/Anesthesia" was approved by the Operative Committee on 07/28/14 and Medical Executive Committee on 08/06/14. The education of physicians was completed on 08/08/14 through Medical Executive Committee, Medical Staff Meeting and Operative Case Committee. The staff was completed on 08/08/14 via unit meetings and a copy of the new policy and consent given to Medical Surgical/ICU/ED/Surgery managers to review with staff not present in meetings.

HOW:

The Quality Manager will monitor compliance: 1. Sample size: Based on Average Daily Census of 37, 30 records will be selected using random selection. 2. The records will be randomly selected by running a list of discharged patient, then selecting every 3rd record until 30 charts are identified. 3. This will be monitored monthly for four consecutive months. 4. The denominator equals the total number of operative permits reviewed. 5. The numerator equals the number of records in which the operative permits were completed correctly. 6. The data will be reported quarterly to the Operative Committee and PI Committee with a compliance of 90% or better by the Director of Quality.

Campbell County HMA, LLC

Organization ID: 3915

923 East Central AvenueLa Follette, TN 37766

Accreditation Activity - 60-day Evidence of Standards Compliance Form

Due Date: 8/25/2014

HAP Standard EC.02.05.01 The hospital manages risks associated with its utility systems.

Findings: EP 8 Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. OBSERVED during the document Review on 6/17/14, the electrical distribution panel next to room 232 (large bottom panel) did not have any panel legend. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. OBSERVED during the building tour on 6/18/14, the electrical distribution panel (Panel PNL"Y") located in room ER117 had breakers 22 and 24 marked as spare breakers. These two breakers were in the on position.

Elements of Performance:

8. The hospital labels utility system controls to facilitate partial or complete emergency shutdowns.

Scoring Category: A

Corrective Action Taken:

WHO:

The Plant Operations Manager is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

The electrical distribution panel next to room 232 (large bottom panel)was labeled with a panel legend on 06/17/14, the day of discovery. The electrical distribution panel (Panel PNL"Y") located in room ER117 had breakers 22 and 24 marked as spare breakers, the old labels were removed and the breaker were re-labeled correctly on 06/18/14. Breakers 22 and 24 were left in the on position after being labeled correctly. Staff was educated by the Plant Operations Manager on the importance of insuring that legends are kept in the panels at all times on 08/13/14 via unit meeting. Staff was educated by the Plant Operations Manager on the importance of verifying that spare breakers are in the off position at all times on 08/13/14 via unit meeting. This will be covered in new employee orientation.

WHEN:

The electrical distribution panel next to room 232 (large bottom panel)was labeled with a panel legend on 06/17/14, the day of discovery. The the electrical distribution panel (Panel PNL"Y") located in room ER117 had breakers 22 and 24 marked as spare breakers, the old labels were removed and the breaker were re-labeled correctly on 06/18/14. Breakers 22 and 24 were left in the on position after being labeled correctly. Staff was educated by the Plant Operations Manager on the importance of insuring that legends are kept in the panels at all times on 08/13/14 via unit meeting. Staff was educated by the Plant Operations Manager on the importance of verifying that spare breakers are in the off position at all times on 08/13/14 via unit meeting. This will be covered in new employee orientation.

HOW:

The Plant Operations Manager will perform annual inspections of the electrical distribution panel(s) and to assess ongoing compliance.

HAP	**Standard EC.02.06.01**	**The hospital establishes and maintains a safe, functional environment. Note: The environment is constructed, arranged, and maintained to foster patient safety, provide facilities for diagnosis and treatment, and provide for special services appropriate to the needs of the community.**

Findings: EP 1 §482.41(c)(2) - (A-0724) - (2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. This Standard is NOT MET as evidenced by: Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/17/14, there was a plug strip (Relocatable Power Tap) located on the floor of OR#1 and used to power patient care equipment. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/17/14, there was a plug strip (Relocatable Power Tap) located on the floor of OR#2 and used to power patient care equipment. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/17/14, there was a plug strip (Relocatable Power Tap) located on the floor of OR#3 and used to power patient care equipment. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/17/14, the electrical distribution panel next to room 232 (large bottom panel) did not have any markings indicating that it was in a PM inventory, it was a normal or emergency panel, etc. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/17/14, room MS231 is a soiled utility room that was unlocked. I asked the organization why it was unlocked when it contained used needle boxes and red bag waste and was in a corridor that was open to hospital visitors. They organization responded that all their soiled utility rooms were unlocked. I requested either a policy or a risk assessment demonstrating that they had considered the issues regarding the needles and the red bag waste. The organization could produce neither one. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/17/14, there were non-hospital grade receptacles in the nurse's station on the 2nd floor. Consequently I asked the organization to show documentation that they were testing these receptacles annually. The organization could provide no evidence that the plugs in question had been tested. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/18/14, the electrical distribution panel located in room ME112 did not have any markings indicating that it was in a PM inventory, it was a normal or emergency panel, etc.

Elements of Performance:

1. Interior spaces meet the needs of the patient population and are safe and suitable to the care, treatment, and services provided.

Scoring Category: C

Corrective Action Taken:

WHO:

The Plant Operations Manager is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

To be in compliance with Joint Commission standards of care EC.02.01.01: The plug strip (Relocatable Power Tap) located on the floor of OR#1, OR#2, and OR#3, used to power patient care equipment was removed on 08/19/14. Longer cords were ordered and added to the equipment on 08/19/14. Safety mats were ordered and put into place in ensure the safety of the operating room staff on 08/19/14. The Director of Surgery educated the staff via unit meeting on 08/20/14 to the above changes in OR# 1,2,&3. The Plant Operations Manager will monitor that relocatable power taps have been removed and are not in use. The electrical distribution panel next to room 232 and ME112 (large bottom panel)was labeled and an annual monitor compliance was completed on 03/18/14. The electrical distribution panel next to room 232 and ME112 (large bottom panel)has been labeled as an emergency panel. A vendor completed an ARC Flash study on all electrical distribution panels on 08/07/14. The Plant Operations Manager will monitor the electrical distribution panels for compliance. All soiled utility rooms had locks installed for safety on 08/22/14. All staff were educated to the locks added to the soiled utility rooms on 08/22/14 during unit meetings and daily huddles by nursing supervisor(s) and unit manager(s). The non-hospital grade receptacles in the nurse's station on the 2nd floor were removed and hospital grade receptacles were installed 08/19/14. The Plant Operations Manager will monitor that the newly installed 20 amp hospital grade receptacles have not been replace with different receptacles.

WHEN:

The plug strip (Relocatable Power Tap) located on the floor of OR#1, OR#2, and OR#3, used to power patient care equipment was removed on 08/19/14. Longer cords were ordered and added to the equipment on 08/19/14. Safety mats were ordered and put into place in ensure the safety of the operating room staff on 08/19/14. The Director of Surgery educated the staff via unit meeting on 08/20/14 to the above changes in OR# 1,2,&3. The Plant Operations Manager will monitor that relocatable power taps have been removed and are not in use. The electrical distribution panel next to room 232 and ME112 (large bottom panel)was labeled and an annual monitor compliance was completed on 03/18/14. The electrical distribution panel next to room 232 and ME112 (large bottom panel)has been labeled as an emergency panel. A vendor completed an ARC Flash study on all electrical distribution panels on 08/07/14. The Plant Operations Manager will monitor the electrical distribution panels for compliance. All soiled utility rooms had locks installed for safety on 08/22/14. All staff were educated to the locks added to the soiled utility rooms on 08/22/14 during unit meetings and daily huddles by nursing supervisor(s) and unit manager(s). The non-hospital grade receptacles in the nurse's station on the 2nd floor were removed and hospital grade receptacles were installed 08/19/14. The Plant Operations Manager will monitor that the newly installed 20 amp hospital grade receptacles have not been replace with different receptacles.

HOW:

The Environment of Care Committee will perform semi-annual environment of care rounds to assess ongoing compliance.

Evaluation

Method: Relocatable Power Taps 1. The Operating Rooms will be checked that Relocatable Power Taps have been removed and are not in use by the Plant Operations Manager. 2. This will be monitored monthly for four (4) consecutive months. 3. The denominator equals the total number of Operating Rooms. 4. The numerator equals the number of Operating Room in compliance. 5. The data will be reported to the Safety Committee quarterly. Electrical Distribution Panel 1. All Electrical Distribution Panel(s) will be selected each month to monitor that they are labeled correctly, spares are in the off position, and legends are posted. Based on a total of 38 Electrical Distribution Panels, 38 panels will be checked each month for 4 months. The selection will be done by selecting all 38 panels on the list of 38. The Plant Operations Manager will monitor the electrical distribution panels for compliance. 2. This will be monitored monthly for four (4) consecutive months. 3. The denominator equals the total number of electrical panels being checked per month. 4. The numerator equals the number of electrical distribution panels being checked per month in compliance. 5. The data will be reported to the Safety Committee quarterly. Soiled Utility Room Locks 1. The soiled utility room(s) will be checked that they are locked. 2. This will be monitored monthly for four (4) consecutive months. 3. The denominator equals the total number of locked soiled utility rooms checked per month. 4. The numerator equals the number of locked soiled utility rooms checked per month in compliance. 5. The data will be reported to the Safety Committee quarterly. Non-Hospital Grade Receptacles 1. The (5)

five newly replaced receptacles will be check that they are hospital grade by The Plant Operations Manger. 2. This will be monitored monthly for four (4) consecutive months. 3. The denominator equals the total number of hospital grade receptacle(s) checked per month. 4. The numerator equals the number of hospital grade receptacle(s) checked per month in compliance. 5. The data will be reported to the Safety Committee quarterly.

Measure of Success Goal (%): 90

HAP Standard LD.04.03.09 **Care, treatment, and services provided through contractual agreement are provided safely and effectively.**

Findings: EP 2 §482.12(e)(2) - (A-0085) - (2) The hospital must maintain a list of all contracted services, including the scope and nature of the services provided. This Standard is NOT MET as evidenced by: Observed in Individual Tracer at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. The services of a compounding pharmacy and pharmacist were utilized at the outpatient infusion center to provide chemotherapy medication. No written agreement for this service was available for review at the time of survey.

Elements of Performance:

2. The hospital describes, in writing, the nature and scope of services provided through contractual agreements.

Scoring Category: A

Corrective Action Taken:

WHO:

The Director of Pharmacy is ultimately responsible for the corrective action and overall and ongoing compliance.

WHAT:

A written agreement between the compounding pharmacy and pharmacist at the infusion center and LaFollette Medical Center was completed on 07/01/14.

WHEN:

A written agreement between the compounding pharmacy and pharmacist at the infusion center and LaFollette Medical Center was completed on 07/01/14.

HOW:

The Director of Pharmacy will assess and maintain ongoing compliance of this contract yearly.

HAP Standard LD.04.04.07 **The hospital considers clinical practice guidelines when designing or improving processes.**

Findings: EP 3 Observed in Individual Tracer at Infusion Ctr a Dept. of LaFollette Medical Ctr (7557 Danaher Way, Powell, TN) site. Observation 1. Observed hospital use of order sets for chemotherapy that were partially preprinted and partially hand written. The process here was for the physician to fax a partially compete order to the infusion center. This order contained multiple medications for multiple treatment sessions. The infusion center nurse would cross medication(s) off the order, then determine

the current BSA, drug and amount of chemotherapy to be administered at the particular patient visit. None of the multiple nursing amendments were authenticated by the nurse or returned to the physician before forwarding to the pharmacy for review and compounding. Per pharmacy staff interviews this practice is inconsistent with hospital policy and practice. Observed in Tracer Activities at Infusion Ctr a Dept. of LaFollette Medical Ctr (7557 Danaher Way, Powell, TN) site. Observation 2. Observed hospital use of order sets for chemotherapy that were partially preprinted and partially hand written. The process here was for the physician to fax a partially compete order to the infusion center. This order contained multiple medications for multiple treatment sessions. The infusion center nurse would cross medication(s) off the order, then determine the current BSA, drug and amount of chemotherapy to be administered at the particular patient visit. None of the multiple nursing amendments were authenticated by the nurse or returned to the physician before forwarding to the pharmacy for review and compounding. Per pharmacy staff interviews this practice is inconsistent with hospital policy and practice. Observed in Tracer Activities at Infusion Ctr a Dept. of LaFollette Medical Ctr (7557 Danaher Way, Powell, TN) site. Observation 3. Observed hospital use of order sets for chemotherapy that were partially preprinted and partially hand written. The process here was for the physician to fax a partially compete order to the infusion center. This order contained multiple medications for multiple treatment sessions. The infusion center nurse would cross medication(s) off the order, then determine the current BSA, drug and amount of chemotherapy to be administered at the particular patient visit. None of the multiple nursing amendments were authenticated by the nurse or returned to the physician before forwarding to the pharmacy for review and compounding. Per pharmacy staff interviews this practice is inconsistent with hospital policy and practice.

Elements of Performance:

3. The hospital manages and evaluates the implementation of the guidelines used in the design or modification of processes.

Scoring Category: A

Corrective Action Taken:

WHO:

The Director of Pharmacy is ultimately responsible for the corrective action and overall and ongoing compliance.

WHAT:

The hospital policy "Medication Orders" was reviewed by the Pharmacy and Therapeutic Committee on 08/01/14 with no changes made to the policy, but recommendation(s) to change the physician order set(s)to be compliant with the Institute For Safe Medication Practices (ISMP)and The American Society of Health-System Pharmacists(ASHP). The physician order set(s)were changed to be more clear and concise with the Institute For Safe Medication Practices (ISMP)and The American Society of Health-System Pharmacists(ASHP) recommendations. The changes to physician order set(s) included all orders are pre-printed with physician(s) to fill in the blank(s), calculate the BSA, calculate the dosage of chemotherapy, and to include the day, date, and dosage of each chemotherapy regime. Any change(s) or clarification(s) are sent back to the physician for a new order; not an altered order. The order(s) are verified by the nurse and pharmacist at the infusion center to insure compliance, before being administered to the patient. The physician order set(s) changes were approved by Pharmacy and Therapeutic Committee on 08/01/14. The physician order set(s) were approved by the Medical Staff and Medical Executive Committee on 08/6/14/ and 08/08/14. Education of the Infusion Center physician(s) and staff was completed on 08/02/14, and will be covered in new employee orientation at the Infusion Center.

WHEN:

The hospital policy "Medication Orders" was reviewed by the Pharmacy and Therapeutic Committee on 08/01/14 with no changes made to the policy, but recommendation(s) to change the physician order set(s)to be compliant with the Institute For Safe Medication Practices (ISMP)and The American Society of Health-System Pharmacists(ASHP). The physician order set(s)were changed to be more clear and concise with the Institute For

Safe Medication Practices (ISMP)and The American Society of Health-System Pharmacists(ASHP) recommendations. The changes to physician order set(s) included all orders are pre-printed with physician(s) to fill in the blank(s), calculate the BSA, calculate the dosage of chemotherapy, and to include the day, date, and dosage of each chemotherapy regime. Any change(s) or clarification(s) are sent back to the physician for a new order; not an altered order. The order(s) are verified by the nurse and pharmacist at the infusion center to insure compliance, before being administered to the patient. The physician order set(s) changes were approved by Pharmacy and Therapeutic Committee on 08/01/14. The physician order set(s) were approved by the Medical Staff and Medical Executive Committee on 08/6/14/ and 08/08/14. Education of the Infusion Center physician(s) and staff was completed on 08/02/14, and will be covered in new employee orientation at the Infusion Center.

HOW:

The nursing supervisor of the infusion center and the designated pharmacist at the infusion center will do random monthly order set audits to assess ongoing compliance.

HAP Standard MS.08.01.01 The organized medical staff defines the circumstances requiring monitoring and evaluation of a practitioner's professional performance.

Findings: EP 1 Observed in Credentialing and Privileging at LaFollette Med Ctr Jacksboro Clinic (3170 Appalachian Highway, Suite 5, Jacksboro, TN) site. observed LIPs (nurse practitioner and physician assistant) performing duties such as physical assessments, interpretations, histories, physicals, and exercising prescriptive authority in out-patient clinics. No focused professional practice evaluation was performed.

Elements of Performance:

1. A period of focused professional practice evaluation is implemented for all initially requested privileges.

Scoring Category: A

Corrective Action Taken:

WHO:

The Chief of Staff is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

The Physician Assistant and Nurse Practitioner that were out of compliance were taken back through the credentialing process, according to the Bylaws. The application process was completed and delivered to the hospital on 09/03/14, and will be taken through the Medical Executive on 09/10/14. No changes have been made to the bylaws which were completed on 06/22/2007. The last time they were taken through the Medical Executive Committee was 08/08/2012 and Medical Staff Committee 08/10/2012. The bylaws are expected to have revisions based on external review and requirement of our recent acquisition. Our current bylaws as the time of survey stated all newly credentialed Licensed Independent Practitioners will have a focused professional practice evaluation (FPPE) completed within 90 days of application approval and appointment in accordance with Medical Staff Bylaws. Focused professional practice evaluation (FPPE) indicators shall be selected during the application approval process by the Credentials Committee and forwarded to the Medical Executive Committee for approval. The Quality Director will collect data based on approved focused professional practice evaluation (FPPE) indicators and present to the Credential Committee upon completion for review.

WHEN:

The Physician Assistant and Nurse Practitioner that were out of compliance were taken back through the credentialing process, according to the Bylaws. The application process was completed and delivered to the hospital on 09/03/14, and will be taken through the Medical Executive on 09/10/14. No changes have been made

to the bylaws which were completed on 06/22/2007. The last time they were taken through the Medical Executive Committee was 08/08/2012 and Medical Staff Committee 08/10/2012. The bylaws are expected to have revisions based on external review and requirement of our recent acquisition. Our current bylaws as the time of survey stated all newly credentialed Licensed Independent Practitioners will have a focused professional practice evaluation (FPPE) completed within 90 days of application approval and appointment in accordance with Medical Staff Bylaws. Focused professional practice evaluation (FPPE) indicators shall be selected during the application approval process by the Credentials Committee and forwarded to the Medical Executive Committee for approval. The Quality Director will collect data based on approved focused professional practice evaluation (FPPE) indicators and present to the Credential Committee upon completion for review.

HOW:

The Credential Committee will assess ongoing compliance of focused professional practice evaluation.

HAP Standard MS.08.01.03 **Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privilege(s), or to revoke an existing privilege prior to or at the time of renewal.**

Findings: EP 2 §482.22(a)(1) - (A-0340) - (1) The medical staff must periodically conduct appraisals of its members. This Standard is NOT MET as evidenced by: Observed in Competency Session at LaFollette Med Ctr Jacksboro Clinic (3170 Appalachian Highway, Suite 5, Jacksboro, TN) site for the Hospital deemed service. Observed LIPs (nurse practitioner and physician assistant) performing duties such as physical assessments, interpretations, histories, physicals, and exercising prescriptive authority in out-patient clinics. No evidence as to what type data was collected to evaluate ongoing professional practice. Likewise, no data type was determined by the individual department or approved by the medical staff. This observation applies to 2 of 2 LIPs who practice in the outpatient clinics as surveyed under this HCO that operate under the same CCN as the main hospital.

Elements of Performance:

2. The process for the ongoing professional practice evaluation includes the following: The type of data to be collected is determined by individual departments and approved by the organized medical staff.

Scoring Category: A

Corrective Action Taken:

WHO:

The Chief of Staff is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

The Physician Assistant and Nurse Practitioner that were out of compliance were taken back through the credentialing process, according to the Bylaws. The application process was completed and delivered to the hospital on 09/03/14, and will be taken through the Medical Executive on 09/10/14. No changes have been made to the bylaws which were completed on 06/22/2007. The last time they were taken through the Medical Executive Committee was 08/08/2012 and Medical Staff Committee 08/10/2012. The bylaws are expected to have revisions based on external review and requirement of our recent acquisition. Current bylaws state, the process for the ongoing professional practice evaluation will be completed at a minimum of every 6 months for all licensed independent practitioners in accordance with Medical Staff Bylaws. The ongoing professional practice evaluation shall be selected during the application process by the Credentials Committee and forwarded to the Medical Executive Committee for approval. The Quality Director will collect data based on approved ongoing professional practice evaluation indicators and present to the Credential Committee upon completion

for review.

WHEN:

The Physician Assistant and Nurse Practitioner that were out of compliance were taken back through the credentialing process, according to the Bylaws. The application process was completed and delivered to the hospital on 09/03/14, and will be taken through the Medical Executive on 09/10/14. No changes have been made to the bylaws which were completed on 06/22/2007. The last time they were taken through the Medical Executive Committee was 08/08/2012 and Medical Staff Committee 08/10/2012. The bylaws are expected to have revisions based on external review and requirement of our recent acquisition. Current bylaws state, the process for the ongoing professional practice evaluation will be completed at a minimum of every 6 months for all licensed independent practitioners in accordance with Medical Staff Bylaws. The ongoing professional practice evaluation shall be selected during the application process by the Credentials Committee and forwarded to the Medical Executive Committee for approval. The Quality Director will collect data based on approved ongoing professional practice evaluation indicators and present to the Credential Committee upon completion for review.

HOW:

The Credential Committee will assess ongoing compliance of the ongoing professional practice evaluation.

HAP Standard NR.02.03.01 The nurse executive directs the implementation of nursing policies and procedures, nursing standards, and a nurse staffing plan(s).

Findings: EP 1 §482.23(a) - (A-0386) - §482.23(a) Standard: Organization The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital. This Standard is NOT MET as evidenced by: Observed in Document Review at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. The nurse executive did not approve, nor was provided the opportunity to approve, nursing related polices where the department did not report directly to her. A non-clinical executive had final authority for some nursing policies such as policy #1679 titled "removal of nonvital tissue from the wound using enzymatic debriding agents" in wound care department and policy #1686 titled "to obliterate dead space, undermining or tunneling to promote wound healing." No evidence was presented at the time of survey to suggest that the nonclinical executive was designated to approve nursing policies.

Elements of Performance:

1. The nurse executive or designee approves nursing policies; nursing standards of patient care, treatment, and services; and standards of nursing practice for the hospital before implementation. (See also LD.04.01.07, EP 1)

Scoring Category: A

Corrective Action Taken:

WHO:

The Chief Nursing Executive is ultimately responsible for the corrective action and overall ongoing compliance.

WHAT:

All fifty-four(54) of the wound care policies and/or procedures were approved by the Chief Nursing Executive on 06/18/14. Policies had previously been approved by the Chief Operating Officer. On 06/18/14 the revised organizational chart showing a dotted line responsibility of the Wound Care Nurse to the Chief Nursing

Executive was completed and left for the surveyor to review on 06/19/14.

WHEN:

All fifty-four(54) of the wound care policies and/or procedures were approved by the Chief Nursing Executive on 06/18/14. Policies had previously been approved by the Chief Operating Officer. On 06/18/14 the revised organizational chart showing a dotted line responsibility of the Wound Care Nurse to the Chief Nursing Executive was completed and left for the surveyor to review on 06/19/14.

HOW:

The policies and/or procedures were developed by the certified Wound Care Nurse. Training was provided for the nursing staff by the wound care nurse. The Chief Nursing Executive will review and approve these policies and/or procedure every three (3) years and as needed when changes arise.

HAP Standard RC.01.02.01 Entries in the medical record are authenticated.

Findings: EP 4 §482.24(c)(1) - (A-0450) - (1) All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures. This Standard is NOT MET as evidenced by: Observed in Tracer Activities at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. Observation 1. Observed that scribe entries from June 17, 2014 were not authenticated by the physician at the time of survey. This observation was made on June 18, 2014 after the scribe and provider had left the care area. Observed in Tracer Activities at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. Observation 2. Observed that scribe entries from June 17, 2014 were not authenticated by the physician at the time of survey. This observation was made on June 18, 2014 after the scribe and provider had left the care area. Observed in Tracer Activities at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. Observation 3. Observed that scribe entries from June 17, 2014 were not authenticated by the physician at the time of survey. This observation was made on June 18, 2014 after the scribe and provider had left the care area.

Elements of Performance:

4. Entries in the medical record are authenticated by the author. Information introduced into the medical record through transcription or dictation is authenticated by the author. Note 1: Authentication can be verified through electronic signatures, written signatures or initials, rubber-stamp signatures, or computer key. Note 2: For paper-based records, signatures entered for purposes of authentication after transcription or for verbal orders are dated when required by law or regulation or hospital policy. For electronic records, electronic signatures will be date-stamped. Note 3: For hospitals that use Joint Commission accreditation for deemed status purposes: All orders, including verbal orders, are dated and authenticated by the ordering practitioner or another practitioner who is responsible for the care of the patient, and who, in accordance with hospital policy; law and regulation; and medical staff bylaws, rules, and regulations, is authorized to write orders.

Scoring Category: C

Corrective Action Taken:

WHO:

The Director of the Emergency Department is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

The "Use of Scribes" policy was developed by the Director of the Emergency Department and implemented to include that a physician will authenticate the entry(s) made by scribes before leaving the patient care area. The policy was approved by the Emergency Department Provider Committee. The education of all physicians and scribes were completed via unit meetings and copy of the policy is available to staff and scribes not present. This will be included in orientation for both new physician(s) and scribe(s) in the Emergency Department.

WHEN:

The "Use of Scribes" policy was developed by the Director of the Emergency Department and implemented to include that a physician will authenticate the entry(s) made by scribes before leaving the patient care area. The policy was approved by the Emergency Department Provider Committee on 08/08/14. The education of all physicians and scribes were completed via unit meetings on 08/08/14, and copy of the policy is available to staff and scribes not present. This will be included in orientation for both new physician(s) and scribe(s) in the Emergency Department.

HOW:

The Director of the Emergency Department will monitor compliance: 1. Based on volume of Emergency Room patients and the use of scribes, 50 charts will be selected using random selection. 2. The charts will be randomly selected by running a list of discharged patients during the times a scribe was used, then selecting every 3rd chart until 50 records are identified. 3. This will be monitored monthly for four consecutive months. 4. The denominator equals the total number of scribe entries in the selected records that require authentication. 5. The numerator equals the number of properly authenticated scribe entries per policy. 6. The data will be reported monthly to the Emergency Room Provider Committee.

Evaluation Method: The Director of the Emergency Department will perform: 1. Based on volume of Emergency Room patients and the use of scribes, 50 charts will be selected using random selection. 2. The charts will be randomly selected by running a list of discharged patients during the times a scribe was used, then selecting every 3rd chart until 50 records are identified. 3. This will be monitored monthly for four consecutive months. 4. The denominator equals the total number of scribe entries in the selected records that require authentication. 5. The numerator equals the number of properly authenticated scribe entries per policy. 6. The data will be reported monthly to the Emergency Room Provider Committee.

Measure of Success Goal (%): 90

Campbell County HMA, LLC

Organization ID: 3915

923 East Central AvenueLa Follette, TN 37766

Accreditation Activity - Ten Day Clarification Form

Due Date: 7/10/2014

HAP	**Standard EC.02.03.05**	**The hospital maintains fire safety equipment and fire safety building features. Note: This standard does not require hospitals to have the types of fire safety equipment and building features described below. However, if these types of equipment or features exist within the building, then the following maintenance, testing, and inspection requirements apply.**

Findings: EP 15 §482.41(c)(2) - (A-0724) - (2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. This Standard is NOT MET as evidenced by: Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/17/14, the fire extinguisher in OR#2, had not received its monthly inspection for March 2014. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/17/14, the fire extinguisher in OR#2, had not received its monthly inspection for April 2014. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/17/14, the fire extinguisher in OR#2, had not received its monthly inspection for May 2014. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/17/14, the fire extinguisher in OR#1, had not received its monthly inspection for March 2014. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/17/14, the fire extinguisher in OR#1, had not received its monthly inspection for April 2014. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/17/14, the fire extinguisher in OR#1, had not received its monthly inspection for May 2014.

Elements of Performance:

15. At least monthly, the hospital inspects portable fire extinguishers. The completion dates of the inspections are documented. Note 1: There are many ways to document the inspections, such as using bar-coding equipment, using check marks on a tag, or using an inventory. Note 2: Inspections involve a visual check for the presence and correct type of extinguisher, broken parts, full charge, and ease of access. Note 3: For additional guidance on inspection of fire extinguishers, see NFPA 10, Standard for Portable Fire Extinguishers, 1998 edition (Sections 1-6, 4-3, and 4-4).

Scoring Category: C

Clarification Documentation:

WHO: Title of who is responsible for the corrective action and ongoing compliance. Title of who approved the action, policy, or procedure. Title of who was trained.

The Safety Committee (including the Safety Officer), Chief Engineer and C.O.O. approved the "Fire and Life Safety Documentation" policy.

WHAT: A description of the action taken, of the policy or process and how the element of performance was addressed.

Environment of Care policy "Fire and Life Safety Documentation" was in place at the time of the survey. It defines our process for inspecting and maintaining portable fire extinguishers in accordance with The Joint Commission Environment of Care and related NFPA 10, 1998 standards. Portable fire extinguishers are inspected and inventoried when initially placed in service, and inspected thereafter at approximately 30 day intervals. Monthly inspections include: • Pressure gauge reading or indicator in the operable range or position • Checking for broken or missing safety seals and tamper indicators • Examination for obvious physical damage, corrosion, leakage, or clogged nozzle Extinguishers that fail to meet these requirements of inspection are removed from service and replaced with an extinguisher that has been inspected and validated to meet requirements of this policy. The observations of the surveyor at the time of survey and the small sample size of two fire extinguishers do not accurately reflect the level of compliance for LaFollette Medical Center. The hospital maintains records of all fire extinguisher inspections on the monthly fire extinguisher inspection form. An audit of these inspections was conducted for the previous 12 months prior to survey. As a result of this audit, it is determined that Engineering department conducted 1350 fire extinguisher inspections with 1342 fire extinguishers found to be compliant. This demonstrates a compliance rate of 99%. It should be noted that two fire extinguishers had been added to Operating Rooms 1 & 2 in March and had not been added to the hospital's inventory thus both extinguishers were missed during the months on March, April and May.

WHEN: A date of when each action, policy, procedure, and/or training was completed.

Environment of Care policy "Fire & Life Safety Documentation" was approved in June 25, 2013. We are unable to determine when original policy was approved and implemented.

HOW: A description of how the policy or process was implemented.

Engineering associates are trained on the "Fire and Life Safety Documentation" policy and the proper inspection criteria of fire extinguishers upon hire.

WHY: An explanation of why this information was not reviewed during survey/review.

The surveyor did not review the historical fire extinguisher inspection data to determine our Facility's overall compliance to the standard. The Director of Plant Operations was not given an opportunity to present this data to the survey team prior to survey exit.

HAP Standard EC.02.05.01 The hospital manages risks associated with its utility systems.

Findings: EP 8 Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. OBSERVED during the document Review on 6/17/14, the electrical distribution panel next to room 232 (large bottom panel) did not have any panel legend. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. OBSERVED during the building tour on 6/18/14, the electrical distribution panel (Panel PNL"Y") located in room ER117 had breakers 22 and 24 marked as spare breakers. These two breakers were in the on position.

Elements of Performance:

8. The hospital labels utility system controls to facilitate partial or complete emergency shutdowns.

Scoring Category: A

HAP Standard EC.02.05.07 **The hospital inspects, tests, and maintains emergency power systems. Note: This standard does not require hospitals to have the types of emergency power equipment discussed below. However, if these types of equipment exist within the building, then the following maintenance, testing, and inspection requirements apply.**

Findings: EP 5 §482.41(c)(2) - (A-0724) - (2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. This Standard is NOT MET as evidenced by: Observed in Document Review at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the document Review on 6/17/14, there was not a 30% load test run on the main hospital generator for the month of July 2013. While the monthly test was completed it did not reach the required 30% of the nameplate of the generator (200amps of 600amps) Observed in Document Review at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the document Review on 6/17/14, there was not a 30% load test run on the main hospital generator for the month of October 2013. While the monthly test was completed it did not reach the required 30% of the nameplate of the generator (200 amps of 600 amps) EP 6 §482.41(c)(2) - (A-0724) - (2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. This Standard is NOT MET as evidenced by: Observed in Document Review at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the document Review on 6/17/14, the hospital performed each of it's three transfer tests each month. However they did not record the transfer times as required. They had never done this so none of their testing records showed any transfer times.

Elements of Performance:

5. The monthly tests for diesel-powered emergency generators are conducted with a dynamic load that is at least 30% of the nameplate rating of the generator or meets the manufacturer's recommended prime movers' exhaust gas temperature. If the hospital does not meet either the 30% of nameplate rating or the recommended exhaust gas temperature during any test in EC.02.05.07, EP 4, then it must test the emergency generator once every 12 months using supplemental (dynamic or static) loads of 25% of nameplate rating for 30 minutes, followed by 50% of nameplate rating for 30 minutes, followed by 75% of nameplate rating for 60 minutes, for a total of 2 continuous hours. Note: Tests for non–diesel-powered generators need only be conducted with available load.

Scoring Category: A

Clarification Documentation:

WHO: Title of who is responsible for the corrective action and ongoing compliance. Title of who approved the action, policy, or procedure. Title of who was trained.

Engineering Director and Chief Operating Officer approved the policy "Conditions for Load Testing Emergency Generators".

WHAT: A description of the action taken, of the policy or process and how the element of performance was addressed.

According to policy, Tennova Lafollette Medical Center conducts emergency generator load-testing on a weekly basis. This rigorous load-testing regimen is evidence of Tennova Lafollette Medical Centers commitment to ensuring safe and reliable emergency power systems. Depending on which automatic transfer switch is used to initiate the weekly test, documented amp readings may vary. However, at least monthly a load-test is performed to demonstrate a connected load of greater than 30% of the generators nameplate rating.

WHEN: A date of when each action, policy, procedure, and/or training was completed.

Policy "Conditions for Load Testing Emergency Generators" was last reviewed and approved on 09/24/3013. Policy and process were continued upon review and approval and have been in effect since that time. Facilities

Management staff members (supervisors and senior techs) are trained on this policy and competencies are assessed upon hire and annually. Facilities management personnel who perform emergency generator inspections and testing are specifically educated on the testing procedures as defined by hospital policy "Conditions for Load Testing Emergency Generators". Competencies are available for review in the personnel file maintained on site.

HOW: A description of how the policy or process was implemented.

Facilities Management staff members (supervisors and senior techs) are trained on policy "Conditions for Load Testing Emergency Generators" upon hire and annually thereafter.

WHY: An explanation of why this information was not reviewed during survey/review.

At the time of survey, the surveyor misinterpreted weekly test documentation during July and October of 2013 where one weekly test was missed but the monthly load test was performed and 30% of nameplate rating was achieved. The surveyor's remarks related to 30% load are mathematically inaccurate (i.e. "200 amps of 600 amps)". The full load amp rating of our emergency generator is 625 amps and 30% of this is 187.5 amps. This amperage was achieved during the 2013 July and October monthly load tests as well as all other monthly load tests performed in 2013 and 2014 YTD. Generator monthly load test documentation available upon request.

6. At least monthly, the hospital tests all automatic transfer switches. The completion date of the tests is documented.

Scoring Category: A

Clarification Documentation:

WHO: Title of who is responsible for the corrective action and ongoing compliance. Title of who approved the action, policy, or procedure. Title of who was trained.

Engineering Director and Chief Operating Officer approved the policy "Conditions for Load Testing Emergency Generators".

WHAT: A description of the action taken, of the policy or process and how the element of performance was addressed.

According to policy, at least monthly Tennova Lafollette Medical Center tests all automatic transfer switches and the completion date of the tests is documented. This is substantiated by the surveyor's remarks in our survey report. However, the surveyor's assertion that transfer time must be documented as part of the monthly load-test is unfounded and not supported or required by EC.02.05.07, EP6 or NFPA 110-99.

WHEN: A date of when each action, policy, procedure, and/or training was completed.

Policy "Conditions for Load Testing Emergency Generators" was last reviewed and approved on 09/24/3013. Policy and process were continued upon review and approval and have been in effect since that time. Facilities Management staff members (supervisors and senior techs) are trained on this policy and competencies are assessed upon hire and annually. Facilities management personnel who perform emergency generator inspections and testing are specifically educated on the testing procedures as defined by hospital policy "Conditions for Load Testing Emergency Generators". Competencies are available for review in the personnel file maintained on site.

HOW: A description of how the policy or process was implemented.

Emergency generator load-tests are carried out monthly according to policy. During these tests, all automatic transfer switches are exercised and the results of the test are documented. Staff who perform this test are educated about the related policy and proper testing procedures prior to being assigned the responsibility of testing.

WHY: An explanation of why this information was not reviewed during survey/review.

The surveyor's assertion that transfer time must be documented as part of the monthly load-test is unfounded and not supported or required by EC.02.05.07, EP6 or NFPA 110-99.

HAP Standard EC.02.05.09 **The hospital inspects, tests, and maintains medical gas and vacuum systems. Note: This standard does not require hospitals to have the medical gas and vacuum systems discussed below.**

However, if a hospital has these types of systems, then the following inspection, testing, and maintenance requirements apply.

Findings: EP 1 Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. OBSERVED during the building tour on 6/18/2014, the organization could not produce any records to show that the medical gas master alarm panel in the emergency department had been tested since 2011. The only document available to the surveyor was a report from the bulk oxygen supplier stating that ALL ALARMS HAD BEEN TESTED. This document had no inventory attached to it, no description of a testing interval or the testing procedure. EP 3 Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. OBSERVED during the building tour on 6/17/14, the bulk oxygen storage tank had a source valve that was not labeled as a source valve nor did it indicate what the valve served.

Elements of Performance:

1. In time frames defined by the hospital, the hospital inspects, tests, and maintains critical components of piped medical gas systems, including master signal panels, area alarms, automatic pressure switches, shutoff valves, flexible connectors, and outlets. These activities are documented. (See also EC.02.05.01, EP 3)

Scoring Category: A

Clarification Documentation:

WHO: Title of who is responsible for the corrective action and ongoing compliance. Title of who approved the action, policy, or procedure. Title of who was trained.

The EC.02.05.09. Master Alarm Panel process was approved by the Chief Operating Officer.

WHAT: A description of the action taken, of the policy or process and how the element of performance was addressed.

The EC.02.05.09. Master Alarm Panel process was in place at the time of the survey. This process noted that both master alarm panels would be checked annually by a 3rd party certified oxygen supplier. Documentation given to the TJC surveyor noted that on 12/19/2011, 11/26/2012 & 11/11/2013 the oxygen supplier "checked alarms." The TJC surveyor was made aware that the oxygen supplier verbally verified that both the master alarm panels including the Emergency Department panel had been tested annually. Additional documentation confirming both panels were check annually was received after the survey.

WHEN: A date of when each action, policy, procedure, and/or training was completed.

The EC.02.05.09. Master Alarm Panel process was approved by the Respiratory Director. Vendor documentation confirms that both master panels were tested in 2011, 2012 & 2013.

HOW: A description of how the policy or process was implemented.

The EC.02.05.09. Master Alarm Panel process was in effect at the time of the survey. Annual inspections of the Master Alarm Panels are carried out by a licensed 3rd party professional. Respiratory associates are trained on the Master Alarm Panel process upon hire and as evidenced by daily completion of logs.

WHY: An explanation of why this information was not reviewed during survey/review.

The additional Master Alarm Panel documentation information was not available to the surveyor at the time of survey. The 3rd party vendor verbally verified that both panels had been tested annually however additional documentation was not available until after the surveyor left and is currently available upon request.

3. The hospital makes main supply valves and area shutoff valves for piped medical gas and vacuum systems accessible and clearly identifies what the valves control.

Scoring Category: A

Clarification Documentation:

WHO: Title of who is responsible for the corrective action and ongoing compliance. Title of who approved the action, policy, or procedure. Title of who was trained.

The bulk oxygen source valve label was approved by the Chief Operating Officer.

WHAT: A description of the action taken, of the policy or process and how the element of performance was addressed.

During the building tour, the TJC surveyor felt that the hospital's main oxygen source valve label did not have enough information on the label. The label noted, "Caution - Oxygen Source Valve – Do Not Close Except in an Emergency." It was explained that there was only one bulk oxygen tank and only one oxygen source valve for the entire campus since our hospital and nursing home continuous, physically attached, and share many common systems such as fire alarm, fire sprinkler, and medical gas. It was also mentioned that only Engineering associates and the oxygen vendor had access to this locked area. After the building tour was completed on 06/17/14, the main oxygen source valve label was changed to reflect the TJC surveyor's labeling specifications. The label was changed to, "Caution – Main Oxygen Source Valve – (For the Hospital & Nursing Home) – Do Not Close Except in an Emergency." Both labels were true and accurate at the time of the survey since our hospital and nursing home are physically attached and are serviced by the same bulk oxygen tank.

WHEN: A date of when each action, policy, procedure, and/or training was completed.

The bulk oxygen source valve label was approved by the Chief Operating Officer and was placed on the source valve on 3/17/14. After the building tour was completed on 06/17/14, the main oxygen source valve label was changed to reflect the TJC surveyor's labeling specifications. The label was changed to, "Caution – Main Oxygen Source Valve – (For the Hospital & Nursing Home) – Do Not Close Except in an Emergency."

HOW: A description of how the policy or process was implemented.

The bulk oxygen source valve label was posted at the time of the survey. Engineering associates were trained on the bulk oxygen source valve process in 2013.

WHY: An explanation of why this information was not reviewed during survey/review.

Full access to this documentation was available during the survey but was not requested by the surveyor.

HAP Standard EC.02.06.01 **The hospital establishes and maintains a safe, functional environment. Note: The environment is constructed, arranged, and maintained to foster patient safety, provide facilities for diagnosis and treatment, and provide for special services appropriate to the needs of the community.**

Findings: EP 1 §482.41(c)(2) - (A-0724) - (2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. This Standard is NOT MET as evidenced by: Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/17/14, there was a plug strip (Relocatable Power Tap) located on the floor of OR#1 and used to power patient care equipment. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/17/14, there was a plug strip (Relocatable Power Tap) located on the floor of OR#2 and used to power patient care equipment. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/17/14, there was a plug strip (Relocatable Power Tap) located on the floor of OR#3 and used to power patient care equipment. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/17/14, the electrical distribution panel next to room 232 (large bottom panel) did not have any markings indicating that it was in a PM inventory, it was a normal or emergency panel, etc. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the

Hospital deemed service. OBSERVED during the building tour on 6/17/14, room MS231 is a soiled utility room that was unlocked. I asked the organization why it was unlocked when it contained used needle boxes and red bag waste and was in a corridor that was open to hospital visitors. They organization responded that all their soiled utility rooms were unlocked. I requested either a policy or a risk assessment demonstrating that they had considered the issues regarding the needles and the red bag waste. The organization could produce neither one. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/17/14, there were non-hospital grade receptacles in the nurse's station on the 2nd floor. Consequently I asked the organization to show documentation that they were testing these receptacles annually. The organization could provide no evidence that the plugs in question had been tested. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/18/14, the electrical distribution panel located in room ME112 did not have any markings indicating that it was in a PM inventory, it was a normal or emergency panel, etc.

Elements of Performance:

1. Interior spaces meet the needs of the patient population and are safe and suitable to the care, treatment, and services provided.

Scoring Category: C

HAP Standard IC.02.01.01 The hospital implements its infection prevention and control plan.

Findings: EP 1 §482.42 - (A-0747) - §482.42 Condition of Participation: Condition of Participation: Infection Control This Standard is NOT MET as evidenced by: Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/17/14, the dishwasher log entry for June 1, 2014 was missed for the dinner entry. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. OBSERVED during the building tour on 6/17/14, the dishwasher log entry for June 9, 2014 was missed for the dinner entry. An entry had been recorded and then scratched out with no replacement entry inserted.

Elements of Performance:

1. The hospital implements its infection prevention and control activities, including surveillance, to minimize, reduce, or eliminate the risk of infection.

Scoring Category: C

Clarification Documentation:

WHO: Title of who is responsible for the corrective action and ongoing compliance. Title of who approved the action, policy, or procedure. Title of who was trained.

The "Dishmachine Temperatures" policy was approved by the Dietary Manager as well as the Chief Operating Officer.

WHAT: A description of the action taken, of the policy or process and how the element of performance was addressed.

The "Dishmachine Temperatures" policy was in place at the time of the survey. It defines our process for recording the wash and final rinse temperatures not less than those established by the Food and Drug

Administration. During each period of use, the wash and final rinse temperatures should be recorded on the Dishmachine Temperature Record Form. The observations of the surveyor at the time of survey and the small sample size of a partial month's Dishmachine logs did not accurately reflect the level of compliance for LaFollette Medical Center. The hospital maintains records of the Dishmachine monthly logs. Audits of records were conducted for 05/18/14- 06/16/14. A compliance rate of 94.4% was demonstrated.

WHEN: A date of when each action, policy, procedure, and/or training was completed.

The "Dishmachine Temperatures" policy was reviewed on 06/21/13. We are unable to determine when original policy was approved and implemented. Dishmachine logs dating from February 2013 to current are on file.

HOW: A description of how the policy or process was implemented.

Dietary associates are trained on the "Dishmachine Temperatures" policy upon hire and as evidenced by daily completion of logs.

WHY: An explanation of why this information was not reviewed during survey/review.

The surveyor did not review the historical Dishmachine inspection logs to determine our Facility's overall compliance with the standard. According to the 2009 Food Code, Dishmachine temperatures are required to be taken at the beginning of each period.

HAP Standard LD.04.03.09 Care, treatment, and services provided through contractual agreement are provided safely and effectively.

Findings: EP 2 §482.12(e)(2) - (A-0085) - (2) The hospital must maintain a list of all contracted services, including the scope and nature of the services provided. This Standard is NOT MET as evidenced by: Observed in Individual Tracer at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. The services of a compounding pharmacy and pharmacist were utilized at the outpatient infusion center to provide chemotherapy medication. No written agreement for this service was available for review at the time of survey.

Elements of Performance:

2. The hospital describes, in writing, the nature and scope of services provided through contractual agreements.

Scoring Category: A

HAP Standard LD.04.04.07 The hospital considers clinical practice guidelines when designing or improving processes.

Findings: EP 3 Observed in Individual Tracer at Infusion Ctr a Dept. of LaFollette Medical Ctr (7557 Danaher Way, Powell, TN) site. Observation 1. Observed hospital use of order sets for chemotherapy that were partially preprinted and partially hand written. The process here was for the physician to fax a partially compete order to the infusion center. This order contained multiple medications for multiple treatment sessions. The infusion center nurse would cross medication(s) off the order, then determine the current BSA, drug and amount of chemotherapy to be administered at the particular patient visit. None of the multiple nursing amendments were authenticated by the nurse or returned to the physician before forwarding to the pharmacy for review and compounding. Per pharmacy staff interviews this practice is inconsistent with hospital policy and practice. Observed in Tracer Activities at Infusion Ctr a Dept. of LaFollette Medical Ctr (7557 Danaher Way, Powell, TN) site. Observation 2. Observed hospital use of order sets for chemotherapy that were partially preprinted and partially

hand written. The process here was for the physician to fax a partially compete order to the infusion center. This order contained multiple medications for multiple treatment sessions. The infusion center nurse would cross medication(s) off the order, then determine the current BSA, drug and amount of chemotherapy to be administered at the particular patient visit. None of the multiple nursing amendments were authenticated by the nurse or returned to the physician before forwarding to the pharmacy for review and compounding. Per pharmacy staff interviews this practice is inconsistent with hospital policy and practice. Observed in Tracer Activities at Infusion Ctr a Dept. of LaFollette Medical Ctr (7557 Danaher Way, Powell, TN) site. Observation 3. Observed hospital use of order sets for chemotherapy that were partially preprinted and partially hand written. The process here was for the physician to fax a partially compete order to the infusion center. This order contained multiple medications for multiple treatment sessions. The infusion center nurse would cross medication(s) off the order, then determine the current BSA, drug and amount of chemotherapy to be administered at the particular patient visit. None of the multiple nursing amendments were authenticated by the nurse or returned to the physician before forwarding to the pharmacy for review and compounding. Per pharmacy staff interviews this practice is inconsistent with hospital policy and practice.

Elements of Performance:

3. The hospital manages and evaluates the implementation of the guidelines used in the design or modification of processes.

Scoring Category: A

HAP Standard MM.05.01.01 **A pharmacist reviews the appropriateness of all medication orders for medications to be dispensed in the hospital.**

Findings: EP 8 Observed in Individual Tracer at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. Observed po and IV PRN orders for Zofran without an indication which to formulation to give first. Observed in Tracer Activities at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. Observed po and IV PRN orders for lorazepam without an indication which to give first

Elements of Performance:

8. All medication orders are reviewed for the following: Therapeutic duplication.

Scoring Category: C

HAP Standard MS.03.01.01 **The organized medical staff oversees the quality of patient care, treatment, and services provided by practitioners privileged through the medical staff process.**

Findings: EP 2 §482.12(a)(5) - (A-0049) - [The governing body must:] (5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients; This Standard is NOT MET as evidenced by: Observed in Competency Session at LaFollette Med Ctr Jacksboro Clinic (3170 Appalachian Highway, Suite 5, Jacksboro, TN) site for the Hospital deemed service. observed

LIPs (nurse practitioner and physician assistant) performing duties such as physical assessments ,interpretations, histories, physicals, and exercising prescriptive authority in out-patient clinics. No privileges were granted however, to practice as an LIP in either instance. Interviews with human resources states that they did not believe credentialing was required as these LIPs do not practice at the physical location of the hospital. Both clinics were surveyed under HAP standards and operate under the same CCN and same HCO as the main hospital.

Elements of Performance:

2. Practitioners practice only within the scope of their privileges as determined through mechanisms defined by the organized medical staff.

Scoring Category: A

HAP Standard MS.08.01.01 **The organized medical staff defines the circumstances requiring monitoring and evaluation of a practitioner's professional performance.**

Findings: EP 1 Observed in Credentialing and Privileging at LaFollette Med Ctr Jacksboro Clinic (3170 Appalachian Highway, Suite 5, Jacksboro, TN) site. observed LIPs (nurse practitioner and physician assistant) performing duties such as physical assessments, interpretations, histories, physicals, and exercising prescriptive authority in out-patient clinics. No focused professional practice evaluation was performed.

Elements of Performance:

1. A period of focused professional practice evaluation is implemented for all initially requested privileges.

Scoring Category: A

HAP Standard MS.08.01.03 **Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privilege(s), or to revoke an existing privilege prior to or at the time of renewal.**

Findings: EP 2 §482.22(a)(1) - (A-0340) - (1) The medical staff must periodically conduct appraisals of its members. This Standard is NOT MET as evidenced by: Observed in Competency Session at LaFollette Med Ctr Jacksboro Clinic (3170 Appalachian Highway, Suite 5, Jacksboro, TN) site for the Hospital deemed service. Observed LIPs (nurse practitioner and physician assistant) performing duties such as physical assessments, interpretations, histories, physicals, and exercising prescriptive authority in out-patient clinics. No evidence as to what type data was collected to evaluate ongoing professional practice. Likewise, no data type was determined by the individual department or approved by the medical staff. This observation applies to 2 of 2 LIPs who practice in the outpatient clinics as surveyed under this HCO that operate under the same CCN as the main hospital.

Elements of Performance:

2. The process for the ongoing professional practice evaluation includes the following: The type of data to be collected is determined by individual departments and approved by the organized medical staff.

Scoring Category: A

HAP Standard NPSG.03.06.01 Maintain and communicate accurate patient medication information.

Findings: EP 4 Observed in Individual Tracer at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. The medical record for a patient who had undergone a ophthalmic surgical procedure documented three medications identified at time of admission on the medication reconciliation list. The family physician's history listed six medications in current use. At the time of discharge only three medications were mentioned in the discharge instructions and the record did not document when the next doses were to be taken. Nurses indicated that they had discussed the next doses with the patient at the time of discharge, but did not retain a copy of the information that they provided to the patient. Observed in Individual Tracer at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. The medical record of a patient was reviewed on the day of discharge from the hospital. Two of six medications listed on the admission medication reconciliation list were not referred to at the time of discharge regarding whether or not they were to be taken or when they were to be taken. Nurses indicated that they had discussed four of the six, the ones that they were aware of, but had not documented the discussion.

Elements of Performance:

4. Provide the patient (or family as needed) with written information on the medications the patient should be taking when he or she is discharged from the hospital or at the end of an outpatient encounter (for example, name, dose, route, frequency, purpose). Note: When the only additional medications prescribed are for a short duration, the medication information the hospital provides may include only those medications. For more information about communications to other providers of care when the patient is discharged or transferred, refer to Standard PC.04.02.01.

Scoring Category: C

HAP Standard NR.02.03.01 The nurse executive directs the implementation of nursing policies and procedures, nursing standards, and a nurse staffing plan(s).

Findings: EP 1 §482.23(a) - (A-0386) - §482.23(a) Standard: Organization The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital. This Standard is NOT MET as evidenced by: Observed in Document Review at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. The nurse executive did not approve, nor was provided the opportunity to approve, nursing related polices where the department did not report directly to her. A non-clinical executive had final authority for some nursing policies such as policy

#1679 titled "removal of nonvital tissue from the wound using enzymatic debriding agents" in wound care department and policy #1686 titled "to obliterate dead space, undermining or tunneling to promote wound healing." No evidence was presented at the time of survey to suggest that the nonclinical executive was designated to approve nursing policies.

Elements of Performance:

1. The nurse executive or designee approves nursing policies; nursing standards of patient care, treatment, and services; and standards of nursing practice for the hospital before implementation. (See also LD.04.01.07, EP 1)

Scoring Category: A

HAP Standard PC.02.02.03 The hospital makes food and nutrition products available to its patients.

Findings: EP 6 Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. OBSERVED during the building tour on 6/17/14, the refrigerator/freezer log entry for freezer#8 was absent for June 13, 2014. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. OBSERVED during the building tour on 6/17/14, the refrigerator/freezer log entry for freezer#1 was absent for June 13, 2014. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. OBSERVED during the building tour on 6/17/14, the refrigerator/freezer log entry for freezer#2 was absent for June 13, 2014. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. OBSERVED during the building tour on 6/17/14, the refrigerator/freezer log entry for freezer#3 was absent for June 13, 2014. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. OBSERVED during the building tour on 6/17/14, the refrigerator/freezer log entry for freezer#4 was absent for June 13, 2014. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. OBSERVED during the building tour on 6/17/14, the refrigerator/freezer log entry for freezer#5 was absent for June 13, 2014. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. OBSERVED during the building tour on 6/17/14, the refrigerator/freezer log entry for freezer#6 was absent for June 13, 2014. Observed in Building Tour at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site. OBSERVED during the building tour on 6/17/14, the refrigerator/freezer log entry for freezer#7 was absent for June 13, 2014.

Elements of Performance:

6. The hospital prepares food and nutrition products using proper sanitation, temperature, light, moisture, ventilation, and security.

Scoring Category: C

Clarification Documentation:

WHO: Title of who is responsible for the corrective action and ongoing compliance. Title of who approved the action, policy, or procedure. Title of who was trained.

The "Storage Temperatures" policy was approved by the Dietary Manager as well as the Chief Operating Officer.

WHAT: A description of the action taken, of the policy or process and how the element of performance was addressed.

The "Storage Temperatures" policy was in place at the time of the survey. It defines our process for inspecting, maintaining and recording of temperatures for our freezers and refrigerators. Freezers and refrigerators are inspected and temperatures recorded at the opening and closing of each day. The observations of the surveyor at the time of survey and the small sample size of one partial month's refrigerator/freezer logs did not accurately reflect the level of compliance for LaFollette Medical Center. The hospital maintains records of freezer/refrigerator monthly logs. Audits of these records were conducted for the 05/18/14- 06/16/14. A compliance rate of 97.1% was demonstrated.

WHEN: A date of when each action, policy, procedure, and/or training was completed.

The "Storage Temperatures" policy was reviewed on 6/21/13. We are unable to determine when original policy was approved and implemented. Temperature logs dating from February 2013 to current are on file.

HOW: A description of how the policy or process was implemented.

Dietary associates are trained on the "Storage Temperatures" policy upon hire and as evidenced by daily completion of logs.

WHY: An explanation of why this information was not reviewed during survey/review.

The surveyor did not return to review the historical freezer/refrigerator inspection logs to determine our Facility's overall compliance with the standard. According to the 2009 Food Code, freezers/refrigerators are required to be inspected and temperatures recorded once per day.

HAP Standard RC.01.02.01 Entries in the medical record are authenticated.

Findings: EP 4 §482.24(c)(1) - (A-0450) - (1) All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures. This Standard is NOT MET as evidenced by: Observed in Tracer Activities at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. Observation 1. Observed that scribe entries from June 17, 2014 were not authenticated by the physician at the time of survey. This observation was made on June 18, 2014 after the scribe and provider had left the care area. Observed in Tracer Activities at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. Observation 2. Observed that scribe entries from June 17, 2014 were not authenticated by the physician at the time of survey. This observation was made on June 18, 2014 after the scribe and provider had left the care area. Observed in Tracer Activities at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. Observation 3. Observed that scribe entries from June 17, 2014 were not authenticated by the physician at the time of survey. This observation was made on June 18, 2014 after the scribe and provider had left the care area.

Elements of Performance:

4. Entries in the medical record are authenticated by the author. Information introduced into the medical record through transcription or dictation is authenticated by the author. Note 1: Authentication can be verified through electronic signatures, written signatures or initials, rubber-stamp signatures, or computer key. Note 2: For paper-based records, signatures entered for purposes of authentication after transcription or for verbal orders are dated when required by law or regulation or hospital policy. For electronic records, electronic signatures will be date-stamped. Note 3: For hospitals that use Joint Commission accreditation for deemed status purposes: All orders, including verbal orders, are dated and authenticated by the ordering practitioner or another practitioner who is responsible for the care of the patient, and who, in accordance with hospital policy; law and regulation; and medical staff bylaws, rules, and regulations, is authorized to write orders.

Scoring Category: C

Clarification Documentation:

WHO: Title of who is responsible for the corrective action and ongoing compliance. Title of who approved the action, policy, or procedure. Title of who was trained.

The use of scribes began during the system-wide implementation of MedHost, an electronic medical record system for emergency departments, in fourth quarter 2012 and approved by CEO.

WHAT: A description of the action taken, of the policy or process and how the element of performance was addressed.

Scribes assist emergency department (ED) physicians with documentation in the electronic medical record (EMR) while working in the ED. The primary purpose of the scribe is to allow the physician to maintain patient focus by not only providing documentation but also apprise the physician of workflow statuses and the status of tests performed. While documenting in the EMR, the scribe is responsible for inputting relevant data regarding the physician/patient encounter into the medical record. The scribe cannot transcribe patient orders. Although the scribe inputs data into the medical record, the physician is ultimately responsible for the information contained in the medical record. Each scribe must include an attestation statement at the end of the medical record that identifies the scribe as the person who documented the relevant data into the patient's medical record. This attestation statement must be documented into the EMR prior to the patient's departure from the patient care area and authenticated by the physician prior to the end of the shift. All scribes are trained and proven competent by a third party scribe vendor prior to employment with a personnel file maintained on site. TJC Surveyor's Observations: Observed in Tracer Activities at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. Observation 1. Observed that scribe entries from June 17, 2014 were not authenticated by the physician at the time of survey. This observation was made on June 18, 2014 after the scribe and provider had left the care area. Observed in Tracer Activities at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. Observation 2. Observed that scribe entries from June 17, 2014 were not authenticated by the physician at the time of survey. This observation was made on June 18, 2014 after the scribe and provider had left the care area. Observed in Tracer Activities at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. Observation 3. Observed that scribe entries from June 17, 2014 were not authenticated by the physician at the time of survey. This observation was made on June 18, 2014 after the scribe and provider had left the care area.

WHEN: A date of when each action, policy, procedure, and/or training was completed.

The ED physicians began utilizing scribes in October 2012. ED Provider Meeting minutes on 04/19/13 include a review of the physician's responsibilities as they relate to the use of scribes including documentation guidelines. As of February 2014, for those ED physicians who choose to utilize scribes, those services are provided by a third party scribe vendor with the understanding that all scribes must be trained and proven competent prior to work.

HOW: A description of how the policy or process was implemented.

The information was included in the MedHost training for physicians completed in September/October 2012 and reinforced with all ED physicians in April 2013.

WHY: An explanation of why this information was not reviewed during survey/review.

The surveyor reviewed 3 ED records belonging to one physician. Currently only 3 physicians use scribes. Chart review of 50 May charts involving a random sampling of all 3 physicians was completed. There was a 96% compliance rate pertaining to attestation completed by the physician prior to the end of the shift.

HAP Standard RI.01.03.01 The hospital honors the patient's right to give or withhold informed consent.

Findings:

EP 11 §482.13(b)(2) - (A-0131) - (2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being

able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. This Standard is NOT MET as evidenced by: Observed in Individual Tracer at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for the Hospital deemed service. The hospital's informed consent policy did not include a requirement that there be a discussion regarding the risks related to not receiving the proposed care, treatment and services. Three cases of surgical care were reviewed containing detailed descriptions of the risks, benefits and alternatives of the proposed procedure, but not the risk of not performing the procedure. These included cases of carotid endarterectomy, cataract removal, and peripheral arterial bypass.

Elements of Performance:

11. The informed consent process includes a discussion about reasonable alternatives to the patient's proposed care, treatment, and services. The discussion encompasses risks, benefits, and side effects related to the alternatives and the risks related to not receiving the proposed care, treatment, and services.

Scoring Category: A

was requested by the surveyor at that time. The manufacturer was contacted on 03/04/15, and a response was made on 03/05/15, from the manufacturer, after the surveyor left.

LAB Standard LD.04.01.01 The laboratory complies with law and regulation.

Findings: EP 4 Observed in Document Review at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for CLIA #(s) 44D0659202. The pathologist performed fine needle aspirations on site and the CLIA certificate did not list the subspecialty of cytology.

Elements of Performance:

4. Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificates for nonwaived laboratory testing list all specialties and subspecialties for which the laboratory reports patient results.

Scoring Category: A

LAB Standard QSA.01.01.01 **The laboratory participates in Centers for Medicare & Medicaid Services (CMS)-approved proficiency testing programs for all regulated analytes. Note: This participation in the proficiency testing program includes the specialty of Microbiology, and subspecialties of Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology; the specialty of Diagnostic Immunology, and subspecialties of Syphilis Serology and general Immunology; the specialty of Chemistry, and subspecialties of routine Chemistry, Endocrinology, and Toxicology; the specialty of Hematology (including routine Hematology and Coagulation); the subspecialty of Cytology (limited to gynecologic examinations); and the specialty of Immunohematology (ABO group and Rho(D) typing, unexpected antibody detection, compatibility testing, and antibody identification).**

Findings: EP 5 Observed in Proficiency Testing at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for CLIA #(s) 44D0659202. The laboratory received a score of 60% triglycerides, 0% body fluid triglycerides, 0% RBC (manual), and 60% rheumatoid titer in the third event of 2014. Observed in Proficiency Testing at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for CLIA #(s) 44D0659202. The laboratory received a score of 60% BNP, 40% gram stain, 40% gram stain morphology, and 0% pH (body fluid) in the second event of 2014. The laboratory received a score of 50% pH (amniotic fluid) in the first event of 2014. Observed in Proficiency Testing at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for CLIA #(s) 44D0659202. The laboratory received a score of 50% ESR in the third event of 2013. The laboratory received a score of 80% ABO type, 50% DAT, 0% vaginal wet mount, 0% microalbumin, and 50% pH (amnio fluid) in the second event of 2013. Observed in Proficiency Testing at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for CLIA #(s) 44D0659202. The laboratory received a score of 0% total CO2 and 0% fecal leucocytes in the first event of 2013. The respiratory department received scores of 0% pH, 0% pCO2 and 0% pO2 in the first event of 2013.

Elements of Performance:

5. For each specialty, subspecialty, analyte, or test, the laboratory's proficiency testing results meet satisfactory performance criteria in accordance with law and regulation. Note 1: Satisfactory performance criteria in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), Subpart H, include the following: - Participating in a proficiency testing event. Failure to participate in a proficiency testing event results in a score of 0 for the testing event. - Attaining a score of at least 80% for all specialties, subspecialties, or tests, except ABO group and Rho(D) typing and compatibility testing - Attaining a score of 100% for ABO group and Rho (D) typing or compatibility testing - Returning proficiency testing results to the proficiency testing provider within the time frame specified by that provider. Failure to return proficiency testing results to the proficiency testing provider within the time frame specified by that provider results in a score of 0 for the testing event. - Submitting all results on the proficiency testing form. Omission of results could lead to a failure of attaining the score necessary for satisfactory performance. Note 2: Most proficiency testing events with fewer than 10 participants automatically result in a score of 100% for the event. These challenges are not sufficient for demonstrating that the laboratory has met satisfactory performance criteria. If this occurs, laboratories must supplement with either interlaboratory comparisons as specified under QSA.01.05.01 or non–Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing provided by the instrument manufacturer. (For proficiency testing events in which the laboratory achieves satisfactory performance but has unacceptable proficiency testing results, see also QSA.01.02.01, EP 2)

Scoring Category: C

LAB Standard QSA.01.05.01 The laboratory verifies the accuracy and reliability of results obtained for nonregulated analytes and for those regulated analytes for which compatible proficiency testing samples are not available.

Findings: EP 1 Observed in Proficiency Testing at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for CLIA #(s) 44D0659202. The laboratory did not have policies and procedures that addressed verifying the accuracy and reliability of Platelet Function Test as part of their quality control process.

Elements of Performance:

1. The laboratory has written policies and procedures that include acceptability criteria to verify the accuracy and reliability of results obtained for nonregulated analytes and for those regulated analytes for which compatible proficiency testing samples are not available. Note: Acceptable methods of accuracy verification for nonregulated analytes include the following: - The laboratory uses proficiency testing. - Every six months, the laboratory sends five specimens to a Clinical Laboratory Improvement Amendments of 1988 (CLIA '88)–certified reference laboratory for comparison with its own results. - Interlaboratory quality control results are used to verify the continuing reliability of the tests not included in the proficiency testing program (for example, peer comparisons). - Throughout the year, the technical supervisor of the laboratory retests a random sample of microscopic tests from each staff who performs such testing. - Duplicate testing is performed by two different individuals who perform such tests as reticulocyte counts, urine sediments, and crystal identification.

Scoring Category: A

LAB Standard QSA.02.03.01 The laboratory performs calibration verification.

Findings: EP 2 Observed in Proficiency Testing at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for CLIA #(s) 44D0659202. The respiratory department did not include a minimal and maximum value when they performed a verification of the reportable ranges for blood gas tests. For example, the pCO2 range was verified from 18-101mm Hg while the machine reported 5-115 mm Hg. and the O2 verified range was 0-760 mm Hg and the machine reported values between 0-760 mmHg.

Elements of Performance:

2. The laboratory tests the reportable range of results during the calibration verification process, including a minimal value, a midpoint value, and a maximum value based on the manufacturer's directions and instrument history. Note: The Joint Commission does not require the purchase of commercial linearity kits to meet this requirement. Quality control materials, previously tested proficiency testing samples with known results, and calibration materials are acceptable to use for calibration verification.

Scoring Category: A

LAB Standard QSA.05.18.01 **The organization has policies and procedures to monitor and evaluate the patient and report suspected transfusion-related adverse events.**

Findings: EP 7 Observed in Tracer Activities at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for CLIA #(s) 44D0659202. The organization did not follow their policies and procedures for documentation of blood transfusions in the patient reviewed from December 2014. The date and time each unit was started was not documented on the transfusion form for unit #1, unit #3, unit #4 and unit #5. There was no other documentation of the date transfused on any of the forms. One of the units (platelets) did not have any documentation of a visual check and time of issue documented in the laboratory LIS.

Elements of Performance:

7. The organization follows its policies and procedures that guide the monitoring of the patient and the reporting of suspected transfusion-related adverse events during blood and blood component administration.

Scoring Category: A

LAB Standard WT.01.01.01 **Policies and procedures for waived tests are established, current, approved, and readily available.**

Findings: EP 3 Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site. The package inserts used as policies and procedures for each waived test had not been enhanced to include site specific polices. For example, the quality control frequency and type were not defined for urine pregnancy tests. The procedure for performance and documentation of the occult blood test was not defined. EP 4 Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. The

director listed on the CLIA certificate for the clinic had not approved in writing the policies and procedures for the waived testing nor were the policies and procedures reviewed and signed at least every three years. EP 6 Observed in Document Review at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for CLIA #(s) 44D0659202. The laboratory did not follow the manufacturer's instructions for follow up cultures on all negative Strep A tests. Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. The clinic did not follow the manufacturer's instructions for follow up cultures on all negative Strep A tests. Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. The clinic did not follow the manufacturer's instructions for ensuring that the normal and abnormal quality controls were acceptable prior to performing patient testing for the glucometer. Quality controls performed on the current lot number since January 2015 were out of range. Patient tests were reported and no corrective action was performed. Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. Manufacturer's recommendations for the storage of reagents was not follow in January and February 2015. The temperature of the refrigerator was documented as 1 degree Centigrade on 15 days. The required range was 2-8 degrees Centigrade. Also the documented range for the weekends was 10-30 degrees Centigrade. The clinic did not document any temperatures for the test kits stored in the lab room.

Elements of Performance:

3. If manufacturers' manuals or package inserts are used as the policies or procedures for each waived test, they are enhanced to include specific operational policies (that is, detailed quality control protocols and any other institution-specific procedures regarding the test or instrument).

Scoring Category: A

4. The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or a qualified designee, approves in writing policies and procedures for waived testing at the following times: - Before initial use of the test for patient testing - Periodically thereafter, as defined by the person whose name appears on the CLIA certificate but at least once every three years - When changes in procedures occur (for example, when manufacturers' updates to package inserts include procedural changes or when a different manufacturer is used)

Scoring Category: A

6. Written policies, procedures, and manufacturers' instructions for waived testing are followed. (See also WT.04.01.01, EPs 3-5) Note: Manufacturers' recommendations and suggestions are surveyed as requirements.

Scoring Category: C

LAB	**Standard WT.02.01.01**	**The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate identifies the staff responsible for performing and supervising waived testing. Note 1: Responsible staff may be employees of the organization, contracted staff, or employees of a contracted service. Note 2: Responsible staff may be identified within job descriptions or by listing job titles or individual names.**

Findings: EP 1 Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. The person whose name appeared on the CLIA certificate had not identified in writing the staff responsible for performing all the waived tests in the clinic. EP 2 Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. The person whose name appeared on the CLIA certificate had not identified in writing the staff responsible for supervising all the waived tests in the clinic.

Elements of Performance:

1. The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or a qualified designee, identifies, in writing, the staff responsible for performing waived testing.

Scoring Category: A

2. The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or a qualified designee, identifies, in writing, the staff responsible for supervising waived testing.

Scoring Category: A

LAB Standard WT.03.01.01 Staff and licensed independent practitioners performing waived tests are competent.

Findings: EP 5 Observed in Competency Session at LaFollette Med Ctr Jacksboro Clinic (3170 Appalachian Highway, Suite 5, Jacksboro, TN) site for CLIA #(s) 44D1058087. The clinic did not use two of the above methods to assess and document competency in November/December 2014 on the employee reviewed. The employee performed urine dip stick, urine pregnancy, flu A/B, Strep A and glucometer. Observed in Competency Session at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. The clinic did not use two of the above methods to assess and document competency to perform protime and urine HCG in February 2015 on the employee reviewed. Only a direct observation was documented. Observed in Competency Session at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. The clinic did not use two of the above methods to assess and document competency on the physician reviewed who performed fecal and gastric occult blood tests. The organization had not used the credentialing process in lieu of annual competency assessment to document training and competency.

Elements of Performance:

5. Competency for waived testing is assessed using at least two of the following methods per person per test: - Performance of a test on a blind specimen - Periodic observation of routine work by the supervisor or qualified designee - Monitoring of each user's quality control performance - Use of a written test specific to the test assessed

Scoring Category: A

LAB Standard WT.05.01.01 The organization maintains records for waived testing.

Findings: EP 1 Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. Internal quality control results were not documented for patient tests for hemoccult tests performed in the clinic. Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. External quality controls were not documented for the current lot number of urine HCG tests. There were no external quality controls documented for the past three lot numbers. Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. External positive and negative quality controls were not documented for the current lot number of StrepA tests opened in February 2015. . Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. External negative quality controls were not documented for the current and past two lot numbers of Flu A/B tests. EP 3 Observed in Tracer Activities at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. For the protime/INR reviewed at the clinic, the normal values (normal patient reference interval) did not accompany the patient results documented in the Athena EMR. Observed in Tracer Activities at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. For the finger stick glucose reviewed at the clinic, the normal values (normal patient reference interval) did not accompany the patient results documented in the Athena EMR. EP 4 Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. There was no audit trail for associating the tests results and internal quality control with each lot number of strips used in the Coaguchek XS. The lot number of strips were not documented. Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. There was no audit trail for associating the tests results and external quality control with each lot number of strips used in the glucometer. The lot numbers of of the normal and abnormal quality controls were not documented. Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. There was no audit trail for associating the tests results and internal quality control with each lot number of hemoccult cards used. The lot number of the hemoccult kit was not documented.

Elements of Performance:

1. Quality control results, including internal and external controls for waived testing, are documented. Note 1: Internal quality controls may include electronic, liquid, or control zone. External quality controls may include electronic or liquid. Note 2: Quality control results may be located in the clinical record.

Scoring Category: C

3. Quantitative test result reports in the patient's clinical record for waived testing are accompanied by reference intervals (normal values) specific to the test method used and the population served. (See also DC.02.03.01, EP 14) Note 1: Semiquantitative results, such as urine macroscopic and urine dipsticks, are not required to comply with this element of performance. Note 2: If the reference intervals (normal values) are not documented on the same page as and adjacent to the waived test result, they must be located elsewhere within the patient's permanent clinical record. The result must have a notation directing the reader to the location of the reference intervals (normal values) in the patient's clinical record.

Scoring Category: A

4. Individual test results for waived testing are associated with quality control results and instrument records.
Note: A formal log is not required, but a functional audit trail is maintained that allows retrieval of individual test results and their association with quality control and instrument records.

Scoring Category: A

Campbell County HMA, LLC

Organization ID: 3915

923 East Central AvenueLa Follette, TN 37766

Accreditation Activity - 45-day Evidence of Standards Compliance Form

Due Date: 4/20/2015

LAB **Standard QSA.05.18.01** **The organization has policies and procedures to monitor and evaluate the patient and report suspected transfusion-related adverse events.**

Findings: EP 7 Observed in Tracer Activities at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for CLIA #(s) 44D0659202. The organization did not follow their policies and procedures for documentation of blood transfusions in the patient reviewed from December 2014. The date and time each unit was started was not documented on the transfusion form for unit #1, unit #3, unit #4 and unit #5. There was no other documentation of the date transfused on any of the forms. One of the units (platelets) did not have any documentation of a visual check and time of issue documented in the laboratory LIS.

Elements of Performance:

7. The organization follows its policies and procedures that guide the monitoring of the patient and the reporting of suspected transfusion-related adverse events during blood and blood component administration.

Scoring Category: A

Corrective Action Taken:

WHO:

The Lab Director is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

"Blood and Blood Products-Transfusion" policy was reviewed with no revisions required. The policy was approved 11/20/2013 by the CNO and the lab medical director. Education is completed with all new employees and ongoing education is completed with nursing annual review. Re-education was started with staff in the February 25,2015 staff meeting, follow-up in service was also done on 04/10/2015. A copy of the policy as well as an example completed blood transfusion form was placed in the communication book and hung at the nurses stations, to reach those nurses not available for staff meetings. Lab Staff were re-educated to the requirement of documenting visual check time of issue by individual education of each laboratory staff member.

WHEN:

The policy was approved 11/01/2013 by the CNO and the lab medical director. Review of the policy by the Lab Director and CNO was completed 03/19/2015. Re-education of staff on the policy requirements was completed 4/10/2015.

HOW:

Monthly chart audits for blood transfusion will be completed by each department manager. The lab director will send out a list of all blood transfusions to each department manager, who then will review for completeness of chart and proper documentation. Based on the number of blood transfusions,which is approximately 30 per month, 100% will be audited and reported to the lab medical director. Any nurse who is

out of compliance with the blood transfusion document will be counseled one on one upon discovery. Monitoring of the blood transfusion sheets will be reported through the Operative Case and Blood Utilization Committee, then reported up through Performance Improvement Committee. Laboratory sign out documentation will be reviewed at least monthly by the Director/designee and the results will be reported to the Case and Blood Utilization Committee as well.

LAB Standard WT.01.01.01 Policies and procedures for waived tests are established, current, approved, and readily available.

Findings: EP 3 Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site. The package inserts used as policies and procedures for each waived test had not been enhanced to include site specific polices. For example, the quality control frequency and type were not defined for urine pregnancy tests. The procedure for performance and documentation of the occult blood test was not defined. EP 4 Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. The director listed on the CLIA certificate for the clinic had not approved in writing the policies and procedures for the waived testing nor were the policies and procedures reviewed and signed at least every three years. EP 6 Observed in Document Review at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for CLIA #(s) 44D0659202. The laboratory did not follow the manufacturer's instructions for follow up cultures on all negative Strep A tests. Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. The clinic did not follow the manufacturer's instructions for follow up cultures on all negative Strep A tests. Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. The clinic did not follow the manufacturer's instructions for ensuring that the normal and abnormal quality controls were acceptable prior to performing patient testing for the glucometer. Quality controls performed on the current lot number since January 2015 were out of range. Patient tests were reported and no corrective action was performed. Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. Manufacturer's recommendations for the storage of reagents was not follow in January and February 2015. The temperature of the refrigerator was documented as 1 degree Centigrade on 15 days. The required range was 2-8 degrees Centigrade. Also the documented range for the weekends was 10-30 degrees Centigrade. The clinic did not document any temperatures for the test kits stored in the lab room.

Elements of Performance:

3. If manufacturers' manuals or package inserts are used as the policies or procedures for each waived test, they are enhanced to include specific operational policies (that is, detailed quality control protocols and any other institution-specific procedures regarding the test or instrument).

Scoring Category: A

Corrective Action Taken:

WHO:

The Laboratory Director is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

All insert sheets are no longer used for the policy and procedure. All site specific procedures performed at the

rural health clinic were approved by the clinic medical director and lab director. An education in-service was completed with the staff personnel and medical director of the clinic on the new policies.

WHEN:

New policies were developed and approval was completed on 3/12/15 An education in-service was completed with the staff personnel and medical director of the clinic on 03/12/2015.

HOW:

Lab director will do annual review of policy and procedures, as well as with any new or revised test method, to monitor current testing and ensure medical director is reviewing and signing policy and procedures every three (3) years.

4. The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or a qualified designee, approves in writing policies and procedures for waived testing at the following times: - Before initial use of the test for patient testing - Periodically thereafter, as defined by the person whose name appears on the CLIA certificate but at least once every three years - When changes in procedures occur (for example, when manufacturers' updates to package inserts include procedural changes or when a different manufacturer is used)

Scoring Category: A

Corrective Action Taken:

WHO:

The Laboratory Director is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

All insert sheets are no longer used for the policy and procedure. All site specific procedures performed at the rural health clinic were approved by the clinic medical director and lab director. An education in-service was completed with the staff personnel and medical director of the clinic.

WHEN:

The new policy and procedures were developed on 03/12/2015 and the medical director approved and signed the policy and procedures on 03/16/2015.

HOW:

Lab director will do annual review of policy and procedures to monitor current testing and ensure medical director is reviewing and signing policy and procedures every three (3) years.

6. Written policies, procedures, and manufacturers' instructions for waived testing are followed. (See also WT.04.01.01, EPs 3-5) Note: Manufacturers' recommendations and suggestions are surveyed as requirements.

Scoring Category: C

Corrective Action Taken:

WHO:

The Laboratory Director is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

1. "Quickvue Strep A" policy was developed and included a statement that all negative results would be sent for a culture. An education in-service was completed with the selected staff personnel and medical director of the clinic on 03/12/2015. 2. "AVIVA Glucometer" policy was developed and included a statement that quality control will be logged daily and if any corrective action needed to be completed will be documented. The previous pre-printed log sheet with incorrect ranges was discarded. A new log sheet with a place to write the ranges in was placed in the book. The QC values noted by the surveyor were within acceptable range, but the incorrect range was noted on the logbook. Staff were educated regarding how to document QC and QC ranges. 3.

A certified room temperature thermometer was purchased. A room monitoring temperature log was developed. Staff educated on the proper readings of the thermometer. The temperature log will be checked daily Monday thru Friday during normal clinic hours. On Friday at the close of clinic hours the meter's minimum and maximum memory will be reset to record temperatures over the weekends. On Monday at the opening of the clinic operations the temperatures over the weekends will be recorded and the memory will again be cleared to start the normal work week. Corrective actions will be documented for all out of ranges. Staff were educated by the Director on documentation requirements, as well as actions required when acceptable temperatures are exceeded.

WHEN:

1. The new policy and procedures were developed on 03/12/2015 and the medical director approved and signed the policy and procedures on 03/16/2015. 2. The new policy and procedures were developed on 03/12/2015 and the medical director approved and signed the policy and procedures on 03/16/2015. 3. The room temp thermometer was put into service on 03/12/2015. Staff was educated on 03/12/2015.

HOW:

1. Lab director will review strep log to ensure all negative strep specimens were sent for culture. 2. Lab director will review glucometer log monthly to ensure all quality control results were within acceptable ranges and corrective action was performed and documented. 3. Lab director will review temperature log monthly to ensure acceptable temperature were maintained, and corrective actions documented if temps not in range. Specific review is defined in the Evaluation Method section below:

Evaluation Method: 1.Sample size is 100% of negative strep tests, number of days glucose testing is performed and number of days in each month that all required temperatures were documented. These numbers will be obtained from both clinic laboratory locations. 2. No selection process as all data in #1 will be included. 3. This will be monitored monthly for four consecutive months. 4. The denominator equals total number of negative strep tests at each clinic + number of days glucose testing was done at each clinic + (number of days in each month times the number of temperatures that must be documented each day) 5. The numerator equals number of negative streps that were sent for culture at each location + number of acceptable glucose controls documented at each location + (number of acceptable temperatures documented times number of days in the month) 6. This data will be reported monthly to the Quality Director.

Measure of Success Goal (%): 90

LAB Standard WT.03.01.01 **Staff and licensed independent practitioners performing waived tests are competent.**

Findings: EP 5 Observed in Competency Session at LaFollette Med Ctr Jacksboro Clinic (3170 Appalachian Highway, Suite 5, Jacksboro, TN) site for CLIA #(s) 44D1058087. The clinic did not use two of the above methods to assess and document competency in November/December 2014 on the employee reviewed. The employee performed urine dip stick, urine pregnancy, flu A/B, Strep A and glucometer. Observed in Competency Session at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. The clinic did not use two of the above methods to assess and document competency to perform protime and urine HCG in February 2015 on the employee reviewed. Only a direct observation was documented. Observed in Competency Session at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. The clinic did not use two of the above methods to assess and document competency on the physician reviewed who performed fecal and gastric occult blood tests. The organization had not used the credentialing process in lieu of annual competency assessment to document training and competency.

Elements of Performance:

5. Competency for waived testing is assessed using at least two of the following methods per person per test: - Performance of a test on a blind specimen - Periodic observation of routine work by the supervisor or qualified designee - Monitoring of each user's quality control performance - Use of a written test specific to the test assessed

Scoring Category: A

Corrective Action Taken:

WHO:

The Medical Director of the Rural Health Clinics is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

Each clinic has two (2) assigned employees to perform testing. The lab director has proved competency by using two (2) of the four (4) required methods. Employees were observed performing finger stick glucose testing, finger stick protime, hemoccult/gastric card testing, influenza testing, urine pregnancy, rapid strep testing, and urine dip strip testing, and were given a quiz. A policy was developed for competency, stating all initial hired testing personnel will have competency assessed in this manner. This will be repeated annually and with any new or revised test method. During the educational in service all clinic personnel were instructed that only the selected trained personnel could perform testing, what the competency testing policy required and what their responsibilities were. The Lab Director approved the policy and competency format.

WHEN:

There was verbal, visual and observation training completed on 03/12/2015. The competency quiz was given to the selected employees on 03/12/2015. Competency approved by Medical Director of the Rural Health Clinic on 04/17/2015.

HOW:

The lab director will perform competency testing on all personnel assigned to perform lab testing and any new hires that will be testing,annually thereafter, and with any new tests that may be added. The Lab Director is responsible for insuring competency is attained, documented and maintained.

Campbell County HMA, LLC

Organization ID: 3915

923 East Central AvenueLa Follette, TN 37766

Accreditation Activity - 60-day Evidence of Standards Compliance Form

Due Date: 5/5/2015

LAB Standard IC.01.02.01 **Laboratory leaders designate laboratory resources needed to support the organizationwide infection prevention and control activities.**

Findings: EP 3 Observed in Document Review at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for CLIA #(s) 44D0659202. The organization did not provide the required equipment for performance of the Illumigene test (C.diff) as required by the manufacturer. The manufacturer required following BSC Level 2 recommendations which included a safety hood. (See also IC.01.03.01 ep2)

Elements of Performance:

3. The laboratory provides equipment and supplies for the laboratory services needed to support the organizationwide infection prevention and control program.

Scoring Category: A

Corrective Action Taken:

WHO:

The Lab Director is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

The product insert supplied by the manufacturer states that level two (2) biosafety guidelines must be followed. Evidence shown in the "Biosafety in Microbiological and Biomedical Laboratories", 5th edition manual. Section C: Safety Equipment (Primary Barriers and Personal Protective Equipment), #1 states: "Properly maintained BSCs, other appropriate personal protective equipment, OR other physical containment devices must be used whenever". After doing a risk analysis of the procedure, only the steps prior to heat treatment have the potential to create infectious splashes, because the heat treatment step lyses the cells and renders them non-infectious. Only the step in which the sample prep device is inoculated should fall under this criteria. When vortexing the sample prep it is in a closed system, and when drops are dispensed into the heat treatment tube the sample prep tube is held inside the heat treatment tube when dispensing. This eliminates the potential for splashing. Tests are performed once daily as batch tests with only one person involved in the procedure. The tests are performed behind a closed door in a negative pressure room. Proper person protective equipment is worn at all times including gown, gloves and face protection. Manufacturer's recommended cleaning processes are followed daily for all counters in the room where testing is performed. This process is part of each staff members competency assessment for this test.

WHEN:

In Feb 2012, started using "illumigene c. difficile" DNA Amplification Assay for the detection of cytotoxigenic c. difficile in stool, have been following the manufacturers guidelines since day one of use. Risk analysis survey was completed on 03/23/2015.

HOW:

The laboratory Director is responsible for ongoing compliance by assuring staff follow all safety precautions, use personnel protective equipment appropriately and are competent in all tests performed. The Director/designee do daily observations of staff to assure all safety rules are followed. Any violations are reported via incident report and followed up per facility policy.

LAB Standard LD.04.01.01 The laboratory complies with law and regulation.

Findings: EP 4 Observed in Document Review at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for CLIA #(s) 44D0659202. The pathologist performed fine needle aspirations on site and the CLIA certificate did not list the subspecialty of cytology.

Elements of Performance:

4. Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificates for nonwaived laboratory testing list all specialties and subspecialties for which the laboratory reports patient results.

Scoring Category: A

Corrective Action Taken:

WHO:

The Laboratory Director is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

Pathologist only reports fine needle aspirates at LaFollette Medical Center as adequate or inadequate. No additional descriptions are made. This was discussed with the state CLIA office and they advised us not to add to the CLIA certificate unless we start giving more a more detailed description.

WHEN:

On 03/09/2015 the pathology process for reporting fine needle aspirates were reported as adequate or inadequate only. On 04/06/2015 the state CLIA office advised against updating the CLIA certificated unless we start giving more a more detailed description.

HOW:

The Laboratory Director will review the CLIA certificate every 2 years and as new services are added or deleted to insure it remains accurate.

LAB Standard QSA.01.01.01 **The laboratory participates in Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing programs for all regulated analytes. Note: This participation in the proficiency testing program includes the specialty of Microbiology, and subspecialties of Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology; the specialty of Diagnostic Immunology, and subspecialties of Syphilis Serology and general Immunology; the specialty of Chemistry, and subspecialties of routine Chemistry, Endocrinology, and Toxicology; the specialty of Hematology (including routine Hematology and Coagulation); the subspecialty of Cytology (limited to gynecologic examinations); and the specialty of Immunohematology (ABO group and Rho(D) typing, unexpected antibody detection,**

compatibility testing, and antibody identification).

Findings: EP 5 Observed in Proficiency Testing at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for CLIA #(s) 44D0659202. The laboratory received a score of 60% triglycerides, 0% body fluid triglycerides, 0% RBC (manual), and 60% rheumatoid titer in the third event of 2014. Observed in Proficiency Testing at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for CLIA #(s) 44D0659202. The laboratory received a score of 60% BNP, 40% gram stain, 40% gram stain morphology, and 0% pH (body fluid) in the second event of 2014. The laboratory received a score of 50% pH (amniotic fluid) in the first event of 2014. Observed in Proficiency Testing at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for CLIA #(s) 44D0659202. The laboratory received a score of 50% ESR in the third event of 2013. The laboratory received a score of 80% ABO type, 50% DAT, 0% vaginal wet mount, 0% microalbumin, and 50% pH (amnio fluid) in the second event of 2013. Observed in Proficiency Testing at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for CLIA #(s) 44D0659202. The laboratory received a score of 0% total CO2 and 0% fecal leucocytes in the first event of 2013. The respiratory department received scores of 0% pH, 0% pCO2 and 0% pO2 in the first event of 2013.

Elements of Performance:

5. For each specialty, subspecialty, analyte, or test, the laboratory's proficiency testing results meet satisfactory performance criteria in accordance with law and regulation. Note 1: Satisfactory performance criteria in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), Subpart H, include the following: - Participating in a proficiency testing event. Failure to participate in a proficiency testing event results in a score of 0 for the testing event. - Attaining a score of at least 80% for all specialties, subspecialties, or tests, except ABO group and Rho(D) typing and compatibility testing - Attaining a score of 100% for ABO group and Rho (D) typing or compatibility testing - Returning proficiency testing results to the proficiency testing provider within the time frame specified by that provider. Failure to return proficiency testing results to the proficiency testing provider within the time frame specified by that provider results in a score of 0 for the testing event. - Submitting all results on the proficiency testing form. Omission of results could lead to a failure of attaining the score necessary for satisfactory performance. Note 2: Most proficiency testing events with fewer than 10 participants automatically result in a score of 100% for the event. These challenges are not sufficient for demonstrating that the laboratory has met satisfactory performance criteria. If this occurs, laboratories must supplement with either interlaboratory comparisons as specified under QSA.01.05.01 or non–Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing provided by the instrument manufacturer. (For proficiency testing events in which the laboratory achieves satisfactory performance but has unacceptable proficiency testing results, see also QSA.01.02.01, EP 2)

Scoring Category: C

Corrective Action Taken:

WHO:

The Laboratory Director is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

1.The score of 60% triglycerides in the third event of 2014- This was a result of a bad Cal curve. New results repeated, patients reviewed. First event of 2015 test was 100%. 2.0% body fluid triglycerides in the third event of 2014- This was a result of a bad Cal curve.New results repeated, patients reviewed.Unsuccessful results in the first event of 2015. This low volume test and Laboratory directors decided to send test out from first event 2015 forward. 3. 0% RBC (manual), in the third event of 2014- The lab tech failed to identify the accurate amount of RBC on the cell count. Education video was shown to staff.Staff proved competency by counting QC material. 4.60% rheumatoid titer in the third event of 2014- After reviewing the report on 01/06/2015,for the third event of 2014 the rheumatoid titer was in fact 100%, not 60% as reported by inspector. 5.60% BNP in the second

event of 2014- QC results in on day of testing, but a result of 0 was obtained 3 times during QC. Best explanation is end of one flex and start of another. Proficiency test results out, but difference not clinically significant. Patient results reviewed, no difference noted. 6.40% gram stain and morphology in the second event of 2014- Gram staining technique and interpretation by tech questioned.tech reviewed slides, improved on accuracy, still not 100%. Education on proper gram staining techniques performed by lab manager, education on gram stain morphology performed also. Tech was given blind samples, using new technique, results 100%. 7.0% pH (body fluid) in the second event of 2014- Testing was performed on a newly purchased pH meter. Manufacturer consulted and recommended to not perform pH body fluid on the meter purchased. This was discontinued. 8.50% pH (amniotic fluid) in the first event of 2014- pH paper used had range of 6 and 7, test result of 6.5, discussed with medical director, had personnel reanalyze, acceptable results. 9.50% ESR in the third event of 2013- Improper technique used by tech. Education and demonstration performed on 03/17/2014 by lab manager. 10.80% ABO type in the second event of 2013- Clerical error, tech had A listed on worksheet, but chose O on work form. When results were received, the tech was no longer employed at facility. 11.50% DAT in the second event of 2013- Unable to retest sample due to mishandling after initial testing. When results were received, the tech was no longer employed at facility. 12.0% vaginal wet mount in the second event of 2013- Clue cell criteria questioned on sample, consulted with pathologist. 13.0% micro albumin in the second event of 2013- Clerical error in reporting results to lab director, did not adjust decimal point, first time reporting micro albumin on new chemistry equipment. 14.50% pH (amino fluid) in the second event of 2013- Error due to visual color interpretation of pH paper. On 07/29/2013, discussed with pathologist re: alternate testing methods. 15.0% total CO2 in the first event of 2013- Bias low on all 5 samples, QC reviewed and acceptable. Patient results reviewed, no trends noted. Tech delayed from time of opening sample to testing sample. 16.0% fecal leukocytes in the first event of 2013-Clerical error in reporting results in computer by lab manager. Tech obtained correct results, corrective action secondary review of results before submitting. 17.0% pH, 0% pCO2 and 0% pO2 in the first event of 2013- The yearly order for CAP proficiency testing supplies was ordered in December 2012. Lab also placed an order for the same thing at the same time. The order for the respiratory department was canceled, due to the fact they thought it was a duplicate order. This was not realized until March 2013. CAP was called in April and asked if supplies for proficiency testing could be sent, we were told, no it was too late. An order was placed immediately for the 2nd, 3rd, and 4th Qtr supplies.

WHEN:

1.On 02/13/2015 new Cal curve results repeated, patients reviewed. 2.02/13/2015 new Cal curve results repeated, patients reviewed.Unsuccessful results in the first event of 2015. This low volume test and Laboratory directors decided to send test out from first event 2015 forward. 3. Education video was shown to staff and completed on 12/08/2014, staff proved competency by counting QC material. 5.On 07/10/2014,patient results reviewed, no difference noted. Third event of 2014 the proficiency testing results were noted to be 100%. 6.On 09/23/2014, tech reviewed slides, improved on accuracy, still not 100%. Education on proper gram staining techniques performed by lab manager, education on gram stain morphology performed also. Tech was given blind samples, using new technique, results 100% on 09/23/2014. 7.Patient testing had been performed on 07/16/2014. New meter that had the capability of performing pH was purchased on 07/20/2014. The third event of 2014, pH body fluid performance testing was 100%. 8.Acceptable results obtained on 03/26/2014. 9.Education and demonstration performed on 03/17/2014 by lab manager. 100% accuracy for all 3 events 2014. 10.Third event 2013 was 100%. 07/29/13 random patient selected from employees work history, all results acceptable. 11. Third event 2013 was 100%. 07/29/13 random patient selected from employees work history, all results acceptable. 12.Education performed on 09/09/13. Results 100% in third event. 13.Results were reviewed after decimal point was adjusted and were acceptable on 07/22/2013. 100% since 3rd event 2013. 14.On 07/29/2013, discussed with pathologist re: alternate testing methods. New pH meter was purchased on 07/20/2014. Third event of 2013 results were 100%. 15.Education on 04/29/13 concerning significance of timely testing. Second event of 2013 was 100%. 16.Second event 2013 results 100%. Staffing back to adequate level. 17.An order was placed in March 2013 for the 2nd, 3rd, and 4th Qtr supplies. Proficiency testing was completed for 2nd Qtr in June 2013, 3rd and 4th Qtrs were on time. Results for 2nd, 3rd and 4th Qtrs were 100%.

HOW:

The lab director will monitor all proficiency testing for the lab department and will report to the Performance Improvement Committee Quarterly. The respiratory director will monitor all proficiency testing for the respiratory department and will report to the Performance Improvement Committee Quarterly.

LAB Standard QSA.01.05.01 **The laboratory verifies the accuracy and reliability of results obtained for nonregulated analytes and for those regulated analytes for which compatible proficiency testing samples are not available.**

Findings: EP 1 Observed in Proficiency Testing at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for CLIA #(s) 44D0659202. The laboratory did not have policies and procedures that addressed verifying the accuracy and reliability of Platelet Function Test as part of their quality control process.

Elements of Performance:

1. The laboratory has written policies and procedures that include acceptability criteria to verify the accuracy and reliability of results obtained for nonregulated analytes and for those regulated analytes for which compatible proficiency testing samples are not available. Note: Acceptable methods of accuracy verification for nonregulated analytes include the following: - The laboratory uses proficiency testing. - Every six months, the laboratory sends five specimens to a Clinical Laboratory Improvement Amendments of 1988 (CLIA '88)–certified reference laboratory for comparison with its own results. - Interlaboratory quality control results are used to verify the continuing reliability of the tests not included in the proficiency testing program (for example, peer comparisons). - Throughout the year, the technical supervisor of the laboratory retests a random sample of microscopic tests from each staff who performs such testing. - Duplicate testing is performed by two different individuals who perform such tests as reticulocyte counts, urine sediments, and crystal identification.

Scoring Category: A

Corrective Action Taken:

WHO:

The Laboratory Director is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

The policy "Platelet Function Test" was reviewed and revised to state that "Every six months, the laboratory sends five specimens to a Clinical Laboratory Improvement Amendments of 1988 (CLIA '88)–certified reference laboratory for comparison with its own results." The Reference Laboratory 45 minutes from our facility and uses the same test method. Comparison results must be within manufacturers recommended limits of 15%. The first set of specimens was analyzed and acceptable.

WHEN:

The policy was reviewed and revised the Laboratory Medical Director on 04/28/2015. The laboratory technical specialist was educated on the new process of sending specimens for comparison on 04/28/2015. First set of specimens completed and acceptable 4/30/15.

HOW:

The Laboratory Director made a calendar entry to remind him when these validations are due. Results will be reported to Quality Committee along will other PT information as part of the laboratories Performance Improvement process.

LAB Standard QSA.02.03.01 The laboratory performs calibration verification.

Findings: EP 2 Observed in Proficiency Testing at LaFollette Medical Center (923 East Central Ave., La Follette, TN) site for CLIA #(s) 44D0659202. The respiratory department did not include a minimal and maximum value when they performed a verification of the reportable ranges for blood gas tests. For example, the pCO2 range was verified from 18-101mm Hg while the machine reported 5-115 mm Hg. and the O2 verified range was 0-760 mm Hg and the machine reported values between 0-760 mmHg.

Elements of Performance:

2. The laboratory tests the reportable range of results during the calibration verification process, including a minimal value, a midpoint value, and a maximum value based on the manufacturer's directions and instrument history. Note: The Joint Commission does not require the purchase of commercial linearity kits to meet this requirement. Quality control materials, previously tested proficiency testing samples with known results, and calibration materials are acceptable to use for calibration verification.

Scoring Category: A

Corrective Action Taken:

WHO:

The Respiratory Director is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

The RT Director revised the calibration verification process to include putting the range limits into the IT system so that no results outside these limits could be reported. The Sunquest system used for patient reporting of ABG's was updated with the appropriated low and high ranges. Staff were educated to the new ranges by memo from the RT Director.

WHEN:

On 3/9/2015 the reflection of appropriated low and high reportable ranges were made by Sunquest. Education completed 4/28/15.

HOW:

The Respiratory Director will do bi-annual linearity studies that are approved by the Medical Director. These checks will be performed on all ABG testing. Any changes that need to be made will be done at that time. The Director will review all ABG reports for the presence of these ranges.

LAB	**Standard WT.02.01.01**	**The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate identifies the staff responsible for performing and supervising waived testing. Note 1: Responsible staff may be employees of the organization, contracted staff, or employees of a contracted service. Note 2: Responsible staff may be identified within job descriptions or by listing job titles or individual names.**

Findings:

EP 1 Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. The person whose name appeared on the CLIA certificate had not identified in writing the staff responsible for performing all the waived tests in the clinic. EP 2 Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. The person whose name appeared on the CLIA certificate had not identified in writing the staff responsible for supervising all the waived tests

in the clinic.

Elements of Performance:

1. The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or a qualified designee, identifies, in writing, the staff responsible for performing waived testing.

Scoring Category: A

Corrective Action Taken:

WHO:

The Laboratory Director is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

The Clinic Medical Director put in writing that he designated the laboratory director as the responsible person to determine who is competent to perform waived testing and those individuals were evaluated for competency. The Laboratory Director listed the staff who will perform all tests and the tests they each perform on the staff members competency evaluation form.

WHEN:

Competencies were completed 3/30/15 to list testing staff and tests performed.

HOW:

The Laboratory Director will sign the document indicating the staff are able to perform the test upon completion of their initial or annual competency assessment.

2. The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or a qualified designee, identifies, in writing, the staff responsible for supervising waived testing.

Scoring Category: A

Corrective Action Taken:

WHO:

The Laboratory Director is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

The Clinic Medical Director put in writing that he designated the laboratory administrative director (TS) as the responsible person to supervise the operations of the clinical laboratory.

WHEN:

On 03/05/2015 the delegation letter giving the director supervising responsibility was signed.

HOW:

The delegation letter will be reviewed and signed annually by the Clinic Medical Director and Laboratory Director.

LAB Standard WT.05.01.01 The organization maintains records for waived testing.

Findings:

EP 1 Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave.,

La Follette, TN) site for CLIA #(s) 44D1043189. Internal quality control results were not documented for patient tests for hemoccult tests performed in the clinic. Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. External quality controls were not documented for the current lot number of urine HCG tests. There were no external quality controls documented for the past three lot numbers. Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. External positive and negative quality controls were not documented for the current lot number of StrepA tests opened in February 2015. . Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. External negative quality controls were not documented for the current and past two lot numbers of Flu A/B tests. EP 3 Observed in Tracer Activities at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. For the protime/INR reviewed at the clinic, the normal values (normal patient reference interval) did not accompany the patient results documented in the Athena EMR. Observed in Tracer Activities at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. For the finger stick glucose reviewed at the clinic, the normal values (normal patient reference interval) did not accompany the patient results documented in the Athena EMR. EP 4 Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. There was no audit trail for associating the tests results and internal quality control with each lot number of strips used in the Coaguchek XS. The lot number of strips were not documented. Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. There was no audit trail for associating the tests results and external quality control with each lot number of strips used in the glucometer. The lot numbers of of the normal and abnormal quality controls were not documented. Observed in Document Review at Tennova LaFollette Medical Ctr Clinic (905 E. Central Ave., La Follette, TN) site for CLIA #(s) 44D1043189. There was no audit trail for associating the tests results and internal quality control with each lot number of hemoccult cards used. The lot number of the hemoccult kit was not documented.

Elements of Performance:

1. Quality control results, including internal and external controls for waived testing, are documented. Note 1: Internal quality controls may include electronic, liquid, or control zone. External quality controls may include electronic or liquid. Note 2: Quality control results may be located in the clinical record.

Scoring Category: C

Corrective Action Taken:

WHO:

The Laboratory Director is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

New log sheets for documenting quality control were created for occult blood, urine HCG, Strep A and Influenza tests to document external and internal Quality Control results. Staff was educated and competency proven on documentation of quality control.

WHEN:

On 03/12/2015 education of new log sheets was completed.

HOW:

The laboratory director will perform monthly monitoring of the quality control sheets.

Evaluation Method: 1. Sample size is 100% of tests done at the clinics. 2. This will be monitored monthly for four consecutive months. 3. The denominator equals the total number of tests done at the clinics. 4. The numerator equals the number of tests with acceptable QC documentation. 5. The data will

be reported monthly to the Quality Committee.

Measure of Success Goal (%): 90

3. Quantitative test result reports in the patient's clinical record for waived testing are accompanied by reference intervals (normal values) specific to the test method used and the population served. (See also DC.02.03.01, EP 14) Note 1: Semiquantitative results, such as urine macroscopic and urine dipsticks, are not required to comply with this element of performance. Note 2: If the reference intervals (normal values) are not documented on the same page as and adjacent to the waived test result, they must be located elsewhere within the patient's permanent clinical record. The result must have a notation directing the reader to the location of the reference intervals (normal values) in the patient's clinical record.

Scoring Category: A

Corrective Action Taken:

WHO:

The Laboratory Director is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

Worked with our clinic office software program, Athena, to install the reference ranges in the clinic electronic medical record system (EMR).

WHEN:

A meeting with the Athena on site clinical specialist was held on March 10, 2015 to discuss adding the reference ranges to the EMR. Staff was informed that the reference ranges were being added to the EMR for the clinics. References ranges were updated and completed on April 19, 2015. Random patient reports were viewed to verify that reference ranges were on EMS o 04/23/2015.

HOW:

The clinic director will randomly select patients monthly to verify the reference ranges are present in the EMR and ranges are up to date until compliance is maintained for a full quarter.

4. Individual test results for waived testing are associated with quality control results and instrument records. Note: A formal log is not required, but a functional audit trail is maintained that allows retrieval of individual test results and their association with quality control and instrument records.

Scoring Category: A

Corrective Action Taken:

WHO:

The Laboratory Director is ultimately responsible for the corrective action and for overall and ongoing compliance.

WHAT:

A quality control check log was created to include all necessary items to track quality control results, lot numbers and instrument records. Staff was informed and educated to the new log sheet and how to document on the log sheet by the Lab Director through demonstration.

WHEN:

The quality control check log sheet was completed and put into use on 03/12/2015.

HOW:

The laboratory director will review the quality control log sheet monthly, for completed documentation including lot numbers. Failures will be followed up with individual staff members and reported as part of the clinic laboratory PI process to the Quality Committee.

Board for Licensing Health Care Facilities

State of Tennessee

0000000008

No. of Beds 0066

DEPARTMENT OF HEALTH

This is to certify, that a license is hereby granted by the State Department of Health to

CAMPBELL COUNTY HMA, LLC *to conduct and maintain a*

Hospital TENNOVA HEALTHCARE - LAFOLLETTE MEDICAL CENTER

Located at 923 EAST CENTRAL AVENUE, LAFOLLETTE

County of CAMPBELL *, Tennessee.*

This license shall expire MAY 17 *,* 2016 *, and is subject to the provisions of Chapter 11, Tennessee Code Annotated. This license shall not be assignable or transferable, and shall be subject to revocation at any time by the State Department of Health, for failure to comply with the laws of the State of Tennessee or the rules and regulations of the State Department of Health issued thereunder.*

In Witness Whereof, we have hereunto set our hand and seal of the State this 6TH *day of* MAY *,* 2015 *.*

In the Distinct Category(ies) of: GENERAL HOSPITAL

By Vincent J. Davis, MPH

DIRECTOR, DIVISION OF HEALTH CARE FACILITIES

By John J. Dreyzehner MD

COMMISSIONER

Attachment C, III, Orderly Development, 7

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF CAMPBELL

R. Mark Cain, being first duly sworn, says that he/she is the applicant named in this application or his/her/its lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, *et seq.*, and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete.

SIGNATURE/TITLE CEO

Sworn to and subscribed before me the 12 day of August, 2015, a Notary Public for Campbell County, Tennessee.

STATE OF TENNESSEE NOTARY PUBLIC CAMPBELL COUNTY

Melissa Nash
NOTARY PUBLIC

My commission expires 9/13/15.

State of Tennessee
Health Services and Development Agency
Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

CONSENT CALENDAR

September 1, 2015

Jerry Taylor, Esq.
Burr & Forman
511 Union St, Suite 2300
Nashville, TN 37219

RE: Certificate of Need Application -- Tennova LaFollette Medical Center CN1508-032
To initiate extracorporeal shockwave lithotripsy (ESWL) services up to 3 days/week on the hospital campus through the use of a leased mobile lithotripsy unit. The service area consists of Campbell, Claiborne, and Scott Counties. The estimated project cost is $440,203.

Dear Mr. Taylor:

This is to acknowledge the receipt of supplemental information to your application for a Certificate of Need. Please be advised that your application is now considered to be complete by this office.

Your application is being forwarded to Trent Sansing at the Tennessee Department of Health for Certificate of Need review by the Division of Policy, Planning and Assessment. You may be contacted by Mr. Sansing or someone from his office for additional clarification while the application is under review by the Department. Mr. Sansing's contact information is Trent.Sansing@tn.gov or 615-253-4702.

In accordance with Tennessee Code Annotated, §68-11-1601, et seq., as amended by Public Chapter 780, the 30-day review cycle for **CONSENT CALENDAR** for this project will begin on September 1, 2015. The first thirty (30) days of the cycle are assigned to the Department of Health, during which time a public hearing may be held on your application. You will be contacted by a representative from this Agency to establish the date, time and place of the hearing should one be requested. At the end of the thirty (30)-day period, a written report from the Department of Health or its representative will be forwarded to this office for Agency review within the thirty (30)-day period immediately following. You will receive a copy of their findings. The Health Services and Development Agency will review your application on October 28, 2015. Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. § 68-11-1607(d):

(4) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.

(5) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have questions or require additional information, please contact me.

Sincerely,

Melanie M. Hill
Executive Director

cc: Trent Sansing, TDH/Health Statistics, PPA

State of Tennessee
Health Services and Development Agency
Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

MEMORANDUM

TO: Trent Sansing, CON Director
Office of Policy, Planning and Assessment
Division of Health Statistics
Andrew Johnson Tower, 2nd Floor
710 James Robertson Parkway
Nashville, Tennessee 37243

FROM: Melanie M. Hill
Executive Director

DATE: September 1, 2015

RE: Certificate of Need Application
Tennova LaFollette Medical Center - CN1508-032

Please find enclosed an application for a Certificate of Need for the above-referenced project.

This application has undergone initial review by this office and has been deemed complete. It is being forwarded to your agency for a sixty (60) day review period to begin on September 1, 2015 and end on November 1, 2015.

Should there be any questions regarding this application or the review cycle, please contact this office.

Enclosure

cc: Jerry Taylor, Esq.

LETTER OF INTENT
TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY

The Publication of Intent is to be published in the Knoxville News Sentinel, which is a newspaper of general circulation in Campbell County, Tennessee, on or before August 9, 2015 for one day.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.,* and the Rules of the Health Services and Development Agency, that Tennova Healthcare -- LaFollette Medical Center, owned and managed by Campbell County HMA, LLC, a Tennessee limited liability company, intends to file an application for a Certificate of Need for the initiation of extracorporeal shockwave lithotripsy services through use of a leased mobile lithotripsy unit on a part-time basis on the hospital campus located at 923 East Central Avenue, LaFollette, Campbell County Tennessee. Tennova Healthcare -- LaFollette Medical Center is licensed as a general hospital by the Tennessee Board for Licensing Health Care Facilities. This project involves no change in the number or types of licensed inpatient beds. The estimated project cost is not to exceed $850,000.

The anticipated date of filing the application is August 14, 2015.

The contact person for this project is Jerry W. Taylor, Attorney, who may be reached at: Burr & Forman, LLP, 511 Union Street, Suite 2300, Nashville, Tennessee 37219, 615-724-3247, jtaylor@burr.com.

Signature

8-7-15
Date

==========

The published Letter of Intent contains the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

==========

Supplemental #1
-Original-

TENNOVA LaFollette
(LITHOTRIPSY)

CN1508-032

SUPPLEMENTAL #1
August 27, 2015
1:38 pm

SUPPLEMENTAL RESPONSES

CERTIFICATE OF NEED APPLICATION

FOR

TENNOVA HEALTHCARE - LAFOLLETTE MEDICAL CENTER

Initiation of Part-Time Lithotripsy Service

Campbell County, Tennessee

Project No. CN1508-032

August 27, 2015

Contact Person:

Jerry W. Taylor, Esq.
Burr & Forman, LLP
511 Union Street, Suite 2300
Nashville, Tennessee 37219
615-724-3247

SUPPLEMENTAL #1
August 27, 2015
1:38 pm

1. **Section B, Project Description, Item 1**

Approximately what percentage of lithotripsy procedures will be performed on an emergency basis?

Approximately 10%.

Will Dr. DeLair bill separately for services or will his charges be covered under a global fee?

Dr. DeLair will bill separately for his professional services.

Does Dr. DeLair participate in Medicare and contract with all the TennCare MCOs that the hospital does?

Yes. Dr. DeLair is an employed physician. He participates in Medicare and is in network with all of the TennCare MCOs with which the hospital is in network.

What are the applicant's expectations of physician referrals by specialty to the proposed ESWL mobile service? Please complete the table below.

Specialty	Physicians practicing in PSA/SSA	ESWL Referrals Year 1
Family Practice	26	
Internal Medicine	10	
OB/GYN	2	
Orthopedics	0	
General Surg	8	
Urology	1	165
Other	Podiatry 2 Cardiology 2 Oncology 1	
TOTAL	52	

The number of physicians by specialty is the hospital's estimate based on various sources in the community. There is no such data routinely maintained by TH-LMC.

All referrals from lithotripsy treatment must come from an Urologist. Some portion of the patients will be referred from a different specialty to the Urologist. The vast portion of these referrals will be from Family Practice and Internists, but the applicant was not able to accurately quantify the number of those referrals.

SUPPLEMENTAL #1
August 27, 2015
1:38 pm

2. **Section B, Project Description, Item II. A.**

   Where will the lithotripsy unit be stored when not in use?

   It will be in the possession of the mobile vendor, Kentucky I Lithotripsy, LLC.

   Will the lithotripsy unit be at the hospital full-time or will the vendor be using it at other locations during the week?

   The vendor will be using it at other locations when it is not in use at LaFollette Medical Center.

3. **Section B, Project Description, Item B. II.C.**

   One key benefit appears to be the use of the service as an alternative to invasive surgeries. Can the applicant offer some insight as to the magnitude of same in the PSA and the potential reduction in surgeries resulting from this project?

   Shock wave lithotripsy in an alternative to an invasive surgical procedure which must be performed through the patient's back. Lithotripsy is a very low risk, non- invasive, less painful procedure than the surgical alternative and also results in less lost work time for the patient (if employed). Lithotripsy has a 80-90% success rate, and the benefits to the patient compared to the surgical alternative are numerous and obvious.

   There is no publicly available data as to the number of kidney stone surgeries performed in the service area, so any potential impact on the incidence of such surgical procedures cannot be accurately quantified.

4. **Section B, Project Description, Item E.2**

   Please also describe the date of manufacture of the unit, its current years in service and expected useful life, and any technological advantages in comparison to other ESWL models.

   The date of manufacture is July 2005.

   Its current years in service are 10 years.

   Its expected useful life is 20 plus years.

   Technological advantages in comparison to other ESWL models:

   - Large focus area for enhanced fragmentation and reduced negative effects of respiratory excursion.

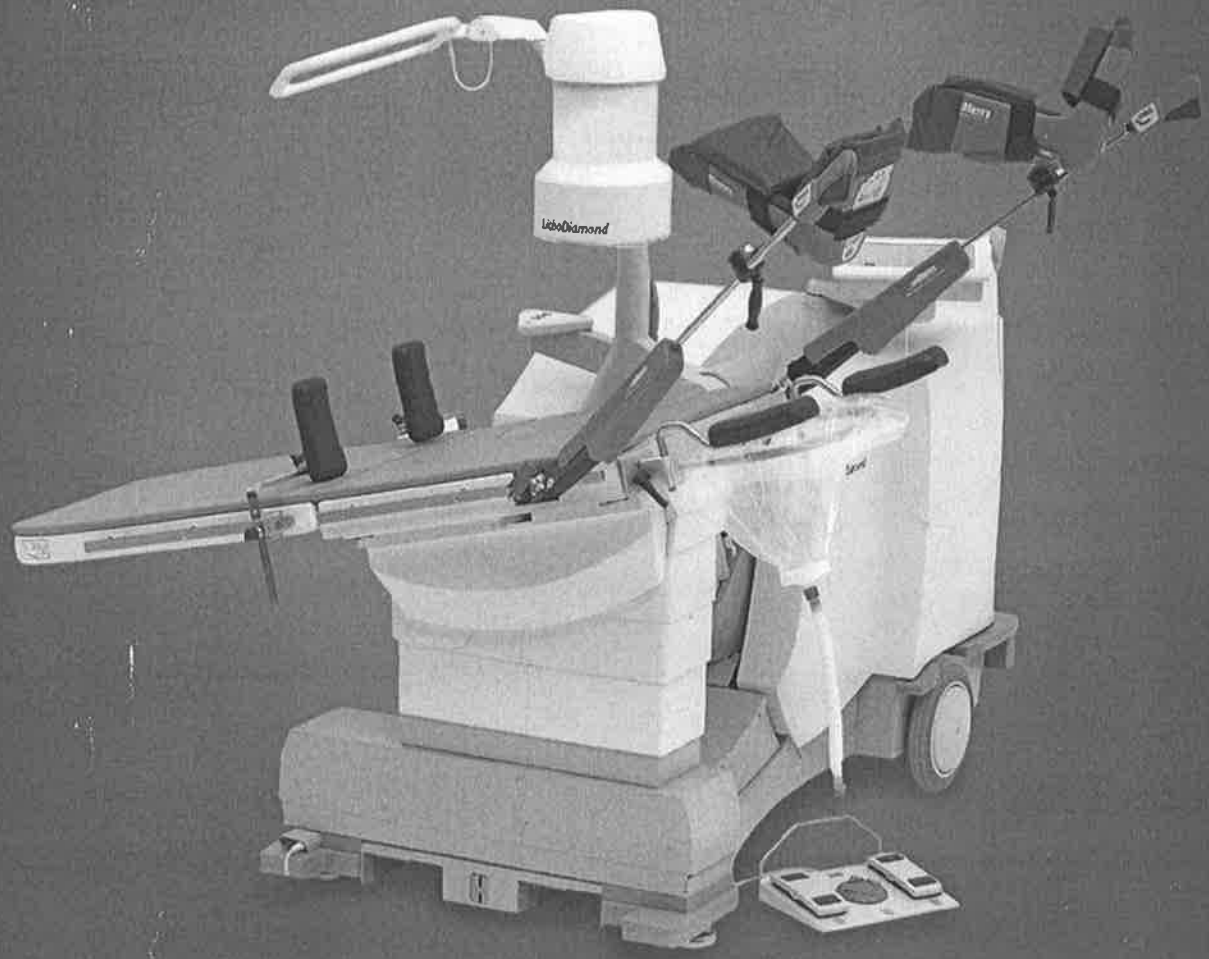
- Allows for additional urological procedures without need to reposition (radio transparent table top).
- +/- trendelenburg positioning.
- Enhanced imaging.

An informational brochure is attached following this response.

SUPPLEMENTAL #1
August 27, 2015
1:38 pm

LITHODIAMOND®

Multifunctional Lithotripsy System

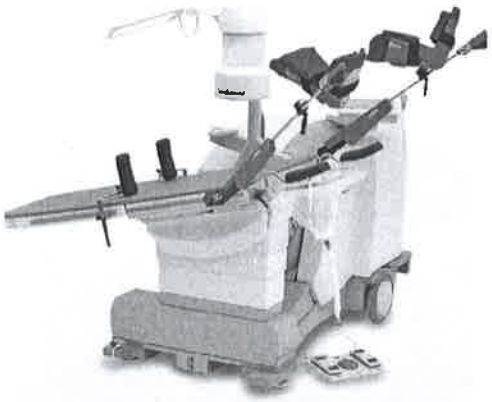


www.healthtronics.com

HealthTronics
We share your passion

A Focused Approach

For two decades, HealthTronics has set the standard with innovative diagnostic and treatment devices like the LithoDiamond® Multifunctional Lithotripsy System. Developed specifically to disintegrate renal and ureteral stones, the LithoDiamond features state-of-the-art technology in a compact design to deliver an exceptionally efficient and affordable lithotripsy system. The LithoDiamond provides the highest level of clinical results for both Urologist and patient.

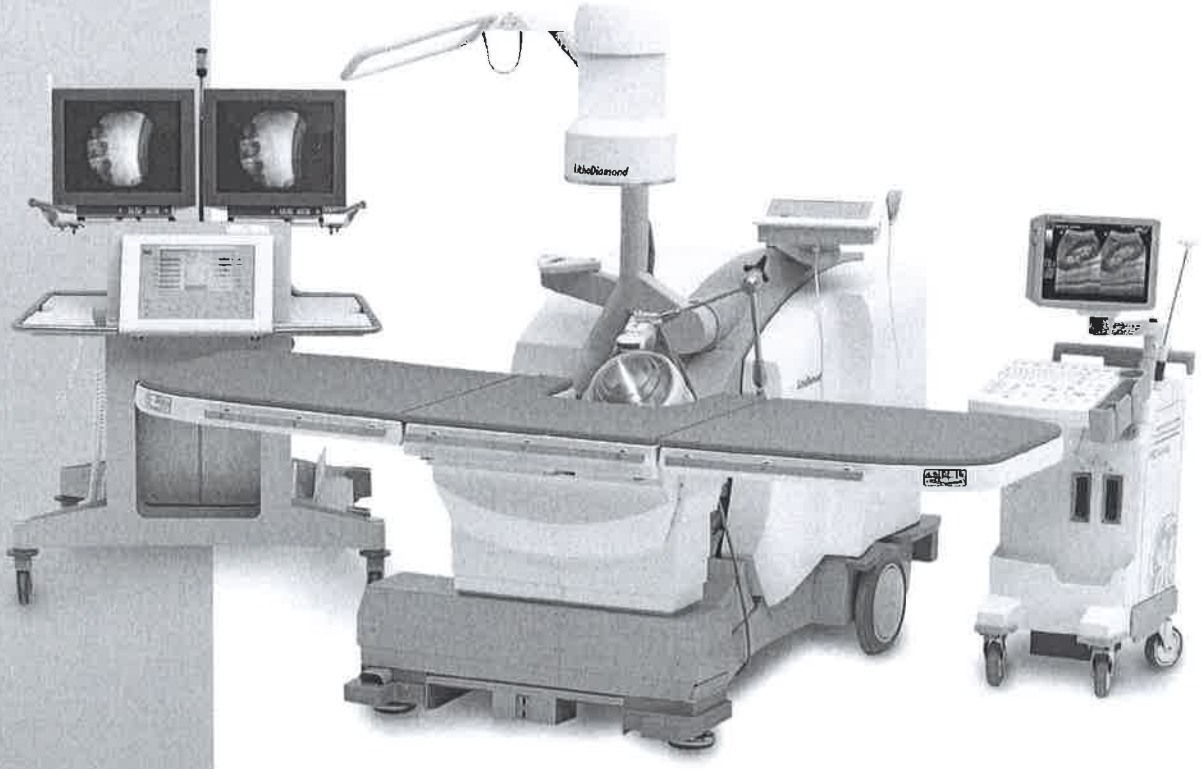


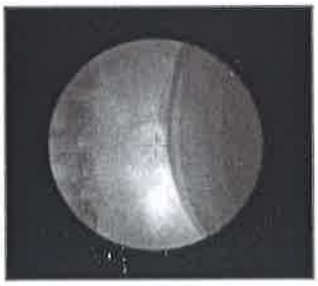
Large Focal Zone

Using proven electrohydraulic shockwave generation, the LithoDiamond delivers safe and effective stone fragmentation. Featuring the largest focal zone (11 x 96 mm) available on the market today, the LithoDiamond provides enhanced fragmentation and dramatically reduces the negative effects of respiratory excursion during the treatment.

Integrated Therapy Modules

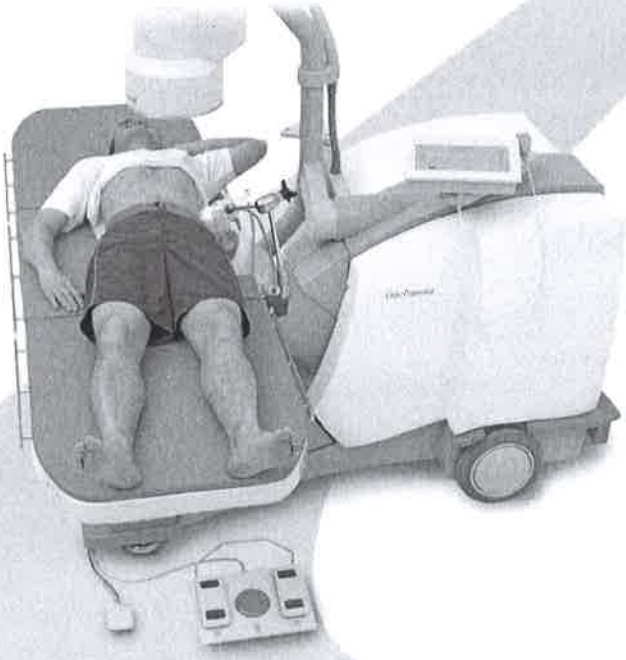
The shockwave generator and x-ray system have been combined with the patient table to form a powerful, yet compact, lithotripsy system. The mobile control console can be positioned in or out of the treatment area and features two high-resolution monitors and a menu system that allows for easier shockwave, x-ray, and table control. An optional remote monitoring system offers even faster service and reduced downtime.

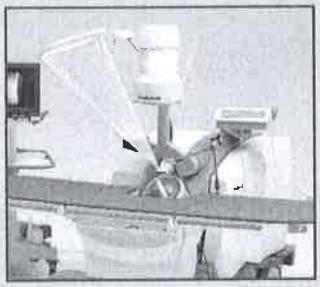




Superb High Resolution Imaging

The LithoDiamond® employs a contrast optimized fluoroscopic imaging system specifically designed for lithotripsy that delivers excellent image resolution with minimum radiation exposure. This makes locating stones and patient positioning much simpler.





A Versatile Urological Workstation

The LithoDiamond allows the operator to perform additional urologic procedures on the table without the need to reposition the patient for treatment.

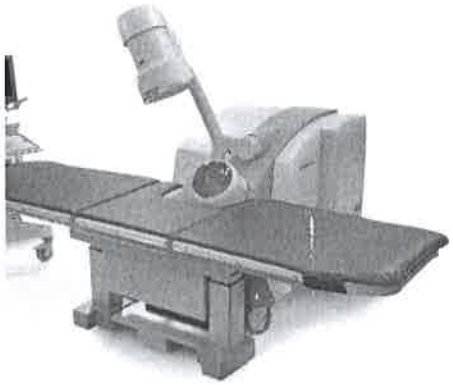
The table provides both positive and negative Trendelenburg tilt, and a foot pedal that allows the operator to reposition the table easily during endoscopic procedures.

The unit is also equipped with stirrups and a flexible holder for disposable drain bags. The optional printer can provide a hard copy of all images during treatment.

Advanced Positioning

The LithoDiamond can also use ultrasonic localization to pinpoint the calculi. The standard transducer for abdominal examinations will localize and position the stone while the computerized system automatically moves the patient into the appropriate treatment position.

Ultrasound and x-ray may be used simultaneously.



Shorter Treatment Times

Because it has been designed specifically for lithotripsy, with a highly advanced locating system, the LithoDiamond has the added advantage of greatly reduced treatment times. With the LithoDiamond, treatment generally takes only 20 or 30 minutes.

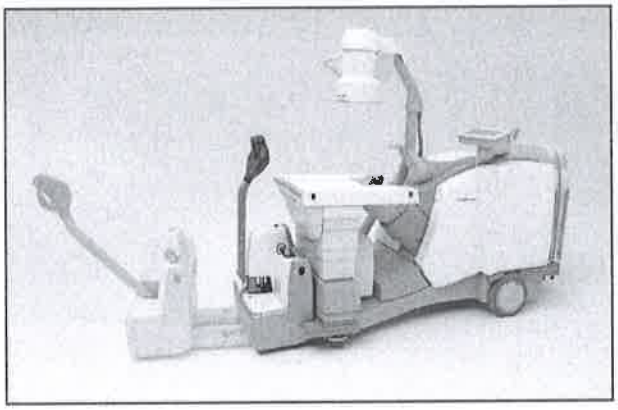
LithoDiamond Features and Benefits

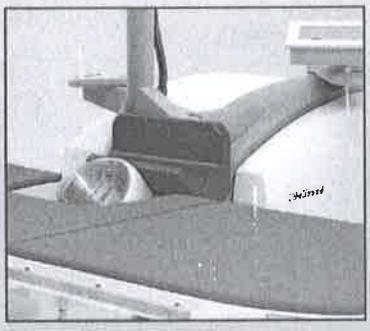
- *Comfortable.* Treatments can be performed without anesthesia.
- *Simple.* A menu-guided user interface makes it easy to control all the unit's functions.
- *Quick and Safe.* Advanced x-ray locating system for simple and accurate stone positioning.
- *Economy.* High availability, short treatment time, and easy servicing for distinct savings over other lithotripsy systems.
- *Patient Convenience.* Low table height for easier patient loading.
- *Flexibility.* Can be used as either a stationary or a transportable system.
- *Multifunctional.* Can be used to perform routine endourology procedures.

The Truly Transportable Lithotripter

The LithoDiamond® is a "Plug and Go" device. Its quick setup and outstanding mobility, a result of the unit's small dimensions and the easily integrated transport unit, make the LithoDiamond a factor you can rely on in your therapy planning.

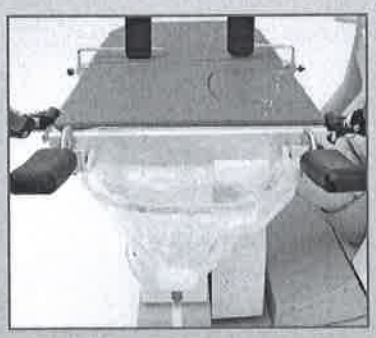
When the treatment day is done, the system becomes a compact configuration, which is easily moved onto a transport vehicle via an electric trolley, or placed into a storage area to free up the treatment area.

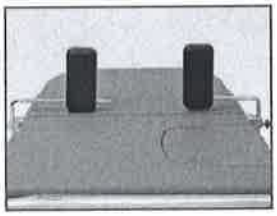


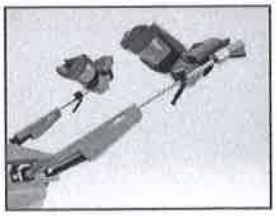


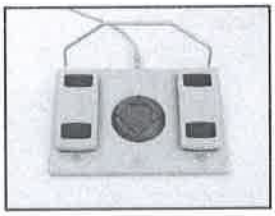
Accessories

- Arm Support
- Holder for Disposable Drain Bags
- Shoulder Supports
- Stirrups
- Foot Pedals









SUPPLEMENTAL #1
August 27, 2015
1:38 pm

Item c – Lease/Contract Cost: given the vendor quote for equipment payments on a $2,400 per procedure basis for an initial term of 1 year, what are the arrangements if for some reason no patients need to be treated on a scheduled day of mobile service? Please clarify what costs the hospital will incur if a patient does not give notice and is a no-show, and the unit comes to the hospital to deliver a service.

If no patients are scheduled for a day the unit is scheduled to be on site at TH-LMC, the mobile vendor will be notified and will not bring the unit. If a patient is scheduled and is a no-show, TH-LMC will not be charged for the procedure. The patient would not incur any liability.

5. **Section C, Need, Item 1.a. (Project Specific Criteria-Extra-Corporeal Shock Wave Lithotripsy). Please provide a response for each of the items noted below:**

3. Current Service Area Utilization. The patient destination chart from the Department of Health is noted. Please contact Alecia Craighead, Statistical Analyst III at the HSDA office with more current and complete data. Please also complete the following chart:

	2012	2013	2014	% Change '12-'14
Total # resident ESWL procedures	163	156	132	-19%
# residents using Knox Co. Providers	112	115	101	-9.8%
% Residents using Knox Co. providers	68.7%	73.7%	76.5%	7.8%
Total ESWL procedures of Knox Co. providers	1,456	1,573	1,439	-1.1%
% Knox Co. provider reliance on PSA/SSA residents	11.2%	9.9%	9.2%	-2%
# residents using Anderson Co. Providers	51	40	31	-39.22%
% Residents	31.3%	25.6%	23.5%	-7.8%

using Anderson Co. providers				
Total ESWL procedures of Anderson Co. providers	212	192	168	-20.7%
% Anderson Co. provider reliance on PSA/SSA residents	24.1%	20.1%	18.4%	-5.7%

Source: HSDA Medical Equipment Registry 8/24/2015

5. Adequate Staffing and Services – Your response to this item is noted. Please:

- **Provide some details regarding radiology services. Please identify the names of all radiologists on the hospital's medical staff that apply (with copy of CV, if possible).**

  The mobile vendor will supply the Radiologic Technologist, who will be properly trained and certified in the operation of the lithotripsy unit. The radiologic technologist has not been specifically identified by the mobile vendor at this time. None of TH-LMC's radiology medical staff will be involved in the provision of lithotripsy services.

- **Please provide documentation of Dr. DeLair's board certification.**

  A letter of verification from The American Board of Urology is attached following this response.

SUPPLEMENTAL #1

August 27, 2015

1:38 pm

THE AMERICAN BOARD OF UROLOGY

600 Peter Jefferson Parkway
Suite 150
Charlottesville, VA 22911

Phone: 434/979-0059 Fax: 434/979-0266

www.abu.org

April 10, 2015

Sean Martin DeLair MD
185 Tatum Point
Somerset KY 42503

Dear Dr. DeLair:

The American Board of Urology verifies that you are a Diplomate.

Your certificate was dated February 28, 2009. Your certificate number is 16501.

Certificates issued by the American Board of Urology on or after January 1, 1985 expire on the anniversary of the date of issue and are valid for ten years only. Your certificate will expire February 28, 2019. A physician who fails to maintain certification by the expiration date is no longer a Diplomate of the Board.

Maintenance of this certificate requires full participation in the American Board of Urology's Maintenance of Certification (MOC) program. You are in compliance with MOC, having successfully completed Levels 1 and 2 in 2011 and 2013, respectively, and you are meeting the requirements of your American Board of Urology certificate.

Sincerely,

Gerald H. Jordan, M.D.
Executive Secretary

GHJ/lrd

SUPPLEMENTAL #1
August 27, 2015
1:38 pm

- **Will Dr. DeLair have physician back-up when on vacation or unavailable for other reasons?**

  Not at this time; Dr. DeLair is the only Urologist on the medical staff. TH-LMC is continuing to explore opportunities that may result in another Urologist joining the medical staff in the future, but no specific plans are in place.

  Because the lithotripsy service will be scheduled for specific days, in most instances it will be possible for Dr. DeLair to schedule any absences around the service. In the rare event that an emergent case presents at the E.D. when Dr. DeLair is not available, the patient would be referred or transferred to a lithotripsy provider of the patient's choice following stabilization.

- **It is understood that Dr. DeLair is board-certified in Urology. Are there other training and credentialing requirements of the American College of Surgeon's Advisory Council for Urology besides board certification? If yes, what are they and document that Dr. DeLair meets those requirements.**

  No additional training or certification is required beyond board certification. Dr. DeLair has performed or supervised lithotripsy procedures for many years prior to joining the medical staff.

- **What will be the ongoing education plan for Dr. DeLair and other staff associated with the lithotripsy service.**

  No on-going education specific to the lithotripsy service is necessary or planned for the staff. All routine annual competencies will be completed for all staff.

10. b. Access- Your response to this item is noted. Please update your response using the more recent data collected from the HSDA equipment registry and use the chart below.

ESWL Use Rates by County per 1,000 Population in Applicant's Service Area

County	2012	2013	2014
Campbell	.19344	.21378	.15190
Claiborne	.12688	.10475	.09814
Scott	.19509	.15464	.16861
Statewide*	.11283	.11689	.12090

Source: HSDA Equipment Registry 8/25/15

*Statewide use rate does not include non-Tennessee residents. This is thought to be the more comparable set of data, since the county use rates obviously do not include non-county residents.

6. **Section C, Need, Item 4.A.**

   Your population table is noted. Please add a column that totals the 3-county service area.

   A revised table is attached following this response.

POPULATION AND DEMOGRAPHICS OF SERVICE AREA					
Variable	Campbell County	Claiborne County	Scott County	Service Area Total	State of Tennessee
Current Year (2015), Age 65+	7,793	6,000	3,615	17,408	1,012,937
Projected Year (2018), Age 65+*	8,122	6,378	3,857	18,357	1,102,413
Age 65+, % Change	4.2%	6.3%	6.7%	5.5%	8.8%
Age 65+, % Total (CY)	18.7%	18.3%	16.5%	18.0%	15.2%
Age 65+, % Total (PY)	19.1%	19.2%	17.5%	18.8%	16.1%
CY, Total Population (2015)	41,783	32,765	21,915	96,463	6,649,438
PY, Total Population (2018)	42,566	33,280	21,969	97,815	6,833,509
Total Pop. % Change	1.9%	1.6%	0.2%	1.4%	2.8%
TennCare Enrollees (July, 2015)	13,151	9,274	7,964	30,389	1,433,687
TennCare Enrollees as a % of Total Population(CY)	31.5%	28.3%	36.3%	31.5%	21.6%
Median Age (2010 Census)	42	41	38	40 (avg.)	38
Median Household Income ('09-'13)	$31,943	$33,229	$28,401	$31,191 (avg.)	$44,298
Population % Below Poverty Level ('09-'13)	23.8%	22.9%	28.3%	25% (avg.)	17.6

Sources: Population,http://tn.gov/health/article/statistics-con; TennCare enrollment, TennCare Bureau website; Age, TACIR County Profiles website; Income and poverty level, Census Bureau QuickFacts.

7. **Section C, Need, Item 4.B.**

   Please provide a response to this item.

   The question and omitted response are reflected below:

4. **A. Describe the demographics of the population to be served by this proposal.**

   A table reflecting the population and demographics of the service area is attached following the previous response.

   B. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

   According to data obtained from the Department of Health, every county in the service area had a higher use rate for lithotripsy services than the state-wide use rate for 2013 (see page 20 of the application).

   According to data from the HSDA Equipment Registry, every county in the service area except for Claiborne County in 2013 and 2014, had a higher use rate for lithotripsy services than the state-wide use rate for the years 2012-2014 (see table in response to Supplemental Question 5).

   Every county in the service area is designated as a Medically Underserved Area by the United States Health Resources and Services Administration (see page 20 of the application).

   There is no existing lithotripsy service in the service area.

   The service area has a disproportionally high share of TennCare enrollees (31.5% service area compared to 21.6% state-wide).

   A locally accessible lithotripsy service will address these special needs. TH-LMC participates in Medicare and contracts with all TennCare MCOs operating in the area.

8. **Section C, Need, Item 5**

   Your response to this item is noted; however since the application has already noted that significant numbers of patients are traveling to Knox and Anderson County lithotripsy providers, please complete the following table utilizing data from the HSDA Equipment Registry.

SUPPLEMENTAL #1
August 27, 2015
1:38 pm

Knox/Anderson Co. ESWL Provider	Distance from TH-LMC*	2012 procedures	2013 procedures	2014 procedures
Methodist Medical Center (Anderson)	34 Miles/ 46 min	212	192	168
Fort Sanders Regional Medical Center (Knox)	39 Miles/ 44 min.	143	163	165
North Knoxville Medical Center (Knox)	30 Miles/ 35 min.	289	349	294
Parkwest Medical Center (Knox)	46 Miles/ 51 min	430	437	484
Physicians Regional Medical Center (Knox)	37 Miles/ 43 min	83	71	54
Turkey Creek Medical Center (Knox)	49 Miles/ 53 min	N/A	65	45
University of Tennessee Medical Center (Knox)	40 Miles/ 46 min.	511	488	397

note: please show in miles & estimated driving time

Sources: Procedures, HSDA Medical Equipment Registry, 8/25/15; Distances and times, Google Maps

9. **Section C, Need, Item 6**

The applicant notes that 148 service area residents sought lithotripsy services. The applicant is projecting 165 patients in Year 1, which would suggest a market share of 100%+. Is this a realistic assumption?

The projected number of patients is believed to be reasonable in light of the following considerations:

The projected 165 patients include not only those from the 3 county primary service area, but some from other counties which do not have a local lithotripsy service. Although the number of patients residing in the secondary service area was not quantified, it is reasonable to assume there will be some in-migration from those areas.

The lack of a locally accessible lithotripsy service may be keeping the numbers of treatments provided to service area residents artificially low, as patients may forego treatment or receive alternative forms of treatment.

Because of the per-click lease arrangement, even if the first year projections are not reached the project will still be economically feasible. And, it will still be providing a much needed new health care service in the service area.

Whole Hospital-Other Expenses – Year 1 and 2 of the Other Expense chart on page 30 have the same entries but different totals. Please make the necessary corrections and submit a revised chart.

A revised Other Expenses chart is attached following this response. The reason the entries are identical for both years is these are fixed, not variable expenses.

SUPPLEMENTAL #1

August 27, 2015
1:38 pm

Projected Whole Hospital

Other Expenses

year 1	year 2
4,244,916	4,244,916
201,380	201,380
5,163,219	5,163,219
1,083,417	1,083,417
675,950	675,950
740,404	740,404
1,918,012	1,918,012
270,820	270,820
191,357	191,357
31,549	31,549
-1,609,208	-1,609,208
12,911,815	12,911,815

Other Revenue

year 1	year 2
$ 16,576.83	$ 16,908.36
$ -	$ -
$ 3,772.23	$ 3,847.68
$ 13,317.73	$ 13,584.08
$ -	$ -
$ 105,243.27	$ 107,348.13
$ 656.61	$ 669.74
$ (2,269.47)	$ (2,314.86)
$ 11,132.80	$ 11,355.46
$ -	$ -
148,430	151,399

SUPPLEMENTAL #1
August 27, 2015
1:38 pm

Lithotripsy Only-Other Expenses - Please provide a detailed Other Expenses Chart.

An itemization of "Other Expenses" for the Projected Data Chart for the Lithotripsy service is attached following this response.

SUPPLEMENTAL #1
August 27, 2015
1:38 pm

Projected Data Chart (Lithotripsy Only)

Other Expenses:	Year 1	Year 2
Mobile Lithotripsy Lease Payments:	$396,000	$407,880

11. Section C, Economic Feasibility, Items 6A and 6 B

Item 6B What is the Medicare allowable fee schedule for the codes listed in your response to 6A?

$3,112

12. Section C, Economic Feasibility, Items 7 and 8

What is the minimum number of procedures needed for the lithotripsy service to breakeven?

Because (1) this is a per click lease arrangement, (2) no capital expenditure is required, and (3) net revenue per treatment exceeds the cost per treatment, it will be profitable even if only one treatment is provided.

13. Section C, Orderly Development, Item 3

What are the estimated FTE requirements for RN, Surgical Tech, and CRNA?

The estimated FTE for each position is .32.

The Wage for the CRNA is approximately 3.5 times the median wage. Please explain.

The $250.00 an hour estimated wage is incorrect. The actual estimated hourly rate is $150.00 an hour. The reason this hourly rate is substantially higher than the median TDLWD rate is the CRNAs providing services for the lithotripsy service will be part-time contracted positions, whereas the TDLWD median wage is presumably based on a full-time position.

In the Projected Data Chart for the lithotripsy service the applicant has allocated $3,486 in Year 1. Is that enough?

This entry on the Projected Data Chart for the Lithotripsy service is incorrect. A revised Projected Data Chart for the Lithotripsy service is attached following this response.

SUPPLEMENTAL #1
August 27, 2015
1:38 pm

PROJECTED DATA CHART (Lithotripsy Only)

Give information for the two (2) years following completion of this proposal. The fiscal year begins in _____.

		Year 1	Year 2
A.	Utilization/Occupancy Data (Specify unit of measure)	165	180
B.	Revenue from Services to Patients		
	1. Inpatient Services		$ -
	2. Outpatient Services	$ 1,540,707.30	$ 1,680,771.60
	3. Emergency Services	$ -	$ -
	4. Other Operating Revenue (Specify) _____		$ -
	Gross Operating Revenue	**$ 1,540,707.30**	**$ 1,680,771.60**
C.	Deductions from Operating Revenue		
	1. Contractual Adjustments	$ 941,054.86	$ 1,055,257.24
	2. Provisions for Charity Care	$ 48,722.92	$ 54,635.72
	3. Provisions for Bad Debt	$ 37,449.52	$ 41,994.24
	Total Deductions	**$ 1,027,227.30**	**$ 1,151,887.20**
NET OPERATING REVENUE		$ 513,480.00	$ 528,884.40
			$ -
D.	Operating Expenses		
	1. Salaries and Wages	$ 18,067.50	$ 19,710.00
	2. Physicians' Salaries and Wages		
	3. Supplies	$ 5,134.80	$ 5,288.84
	4. Taxes		
	5. Depreciation		
	6. Rent		
	7. Interest, other than Capital		
	8. Management Fees:		
	a. Fees to Affiliates		
	b. Fees to Non-Affiliates		
	9. Other Expenses	$ 396,000.00	$ 407,880.00
	Specify: _____		
	Total Operating Expenses	$ 419,202.30	$ 432,878.84
E.	Other Revenue (Expenses)--Net		
	Specify: _____		
NET OPERATING INCOME (LOSS)		$ 94,277.70	$ 96,005.56
F.	Capital Expenditures		
	1. Retirement of Principal		
	2. Interest		
	Total Capital Expenditures	$ -	$ -
NET OPERATING INCOME (LOSS)		$ 94,277.70	$ 96,005.56
LESS CAPITAL EXPENDITURES		$ -	$ -
NOI LESS CAPITAL EXPENDITURES		$ 94,277.70	$ 96,005.56

14. Publishers Affidavit

Your response to this item is noted. We will await the Publishers Affidavit.

The Publisher's Affidavit is attached following this response.

SUPPLEMENTAL #1

August 27, 2015
1:38 pm

To: TENNOVA HEALTHCARE

(Advertising) NOTIFICATION OF INTENT TO APPLY FOR **(Ref No:** 639006)

P.O.#:

PUBLISHER'S AFFID

State of Tennessee }

s.s

County of Knox }

Before me, the undersigned, a Notary Public in and for said
Hurst first duly sworn, according to law, says that he/she is a
Knoxville News-Sentinel, a daily newspaper published at Kn
the advertisement of:

(The Above-Referenc

of which the annexed is a copy, was published in said paper
08/09/15 Sun

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that Tennova Healthcare -- LaFollette Medical Center, owned and managed by Campbell County HMA, LLC, a Tennessee limited liability company, intends to file an application for a Certificate of Need for the initiation of extracorporeal shock-wave lithotripsy services through use of a leased mobile lithotripsy unit on a part-time basis on the hospital campus located at 923 East Central Avenue, LaFollette, Campbell County Tennessee. Tennova Healthcare -- LaFollette Medical Center is licensed as a general hospital by the Tennessee Board for Licensing Health Care Facilities. This project involves no change in the number or types of licensed inpatient beds. The estimated project cost is not to exceed $850,000.

The anticipated date of filing the application is August 14, 2015.

The contact person for this project is Jerry W. Taylor, Attorney, who may be reached at: Burr & Forman, LLP, 511 Union Street, Suite 2300, Nashville, Tennessee 37219, 615-724-3247.

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development Agency
Andrew Jackson Building, Ninth Floor
502 Deaderick Street
Nashville, TN 37243

Pursuant to T.C.A. § 68-11-1607(c)(1): (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

and that the statement of account herewith is correct to the best of his/her knowledge, information, and belief.

Sandy Hurst

Subscribed and sworn to before me this 10th day of August 2015

Ashley Breeden

Notary Public

My commission expires _____ 20_____

ASHLEY BREEDEN
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF KNOX

MY COMMISSION EXPIRES:
MAY 5, 2019

15. Annual Progress Reports-Tennova

CN1106-019 – Mercy Health System, Inc. fka Mercy Medical Center North and currently known as North Knoxville Medical Center-Acquisition of a second linear accelerator. According to the last project update (7/30/2015) a request will be asking for a one year extension to the expiration date, which is December 1, 2015. When does the applicant expect to make that request?

The extension request will be made no later than October 30, 2015.

SUPPLEMENTAL #1
August 27, 2015
1:38 pm

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF CAMPBELL

NAME OF FACILITY: TENNOVA HEALTHCARE-LAFOLLETTE MEDICAL CENTER

I, Mark Cain, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

CEO
Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 27 day of August 2015, witness my hand at office in the County of Campbell, State of Tennessee.

Melissa Dash
NOTARY PUBLIC

My commission expires 9/13/15.

Supplemental #2
-Original-

TENNOVA LaFollette
(LITHOTRIPSY)

CN1508-032

SECOND SUPPLEMENTAL RESPONSES

CERTIFICATE OF NEED APPLICATION

FOR

TENNOVA HEALTHCARE - LAFOLLETTE MEDICAL CENTER

Initiation of Part-Time Lithotripsy Service

Campbell County, Tennessee

Project No. CN1508-032

August 31, 2015

Contact Person:

Jerry W. Taylor, Esq.
Burr & Forman, LLP
511 Union Street, Suite 2300
Nashville, Tennessee 37219
615-724-3247

SUPPLEMENTAL #2
August 31, 2015
8:49 am

1. **Section C, Economic Feasibility, Item 4 (Projected Data Charts)**

   Whole Hospital-Other Expenses – The charts submitted do not include the column that identifies the expense item. Please submit a revised page that includes this information.

   A revised Other Expenses chart is attached.

   Lithotripsy Only-Other Expenses – When taking the mobile lithotripsy lease expense for Year 2 and dividing it by 180 procedures, the result is $2,266. Since the "per click" arrangement is for $2,400, please explain this variance. Please also note that if an adjustment is required for this chart, an adjustment will also likely be needed in the Projected Data Chart as well. For example the net revenue per procedure for Year 2 is $2,938.24 instead of the $3,112.54 listed in other parts of the application.

   A revised Projected Data Chart and Other Expenses page are attached. The incorrect "other expenses" entry for Year 2 does not affect the net revenue per case, because the is not a component of the netted out entries from gross revenue. However, it was discovered that certain other entries for Year 2 were also incorrect.

   The attached revised Projected Data Chart reflects a net operating income of $3,112 for both Year 1 and Year 2.

SUPPLEMENTAL #2

August 31, 2015
8:49 am

PDC Whole Hospital — Other Expenses

	year 1	year 2
benefits	4,244,916	4,244,916
prof. fees	201,380	201,380
purchased services	5,163,219	5,163,219
repairs & maint	1,083,417	1,083,417
utilities	675,950	675,950
general insurance	740,404	740,404
other taxes	1,918,012	1,918,012
property tax	270,820	270,820
sales tax	191,357	191,357
marketing, travel, etc.	31,549	31,549
Hitech Incentive	-1,609,208	-1,609,208
	12,911,815	12,911,815

Other Revenue

	year 1	year 2
MEDICAID SETTLEMENT	$ 16,576.83	$ 16,908.36
GIFT SHOP SALES	$ 3,772.23	$ 3,847.68
VENDING	$ 13,317.73	$ 13,584.08
OTHER RENTAL INCOME	$ 105,243.27	$ 107,348.13
MEDICAL TRANSCRIPTS	$ 656.61	$ 669.74
INTEREST INCOME	$ (2,269.47)	$ (2,314.86)
MISC. REFUNDS & REBATES	$ 11,132.80	$ 11,355.46
	148,430	151,399

SUPPLEMENTAL #2

August 31, 2015

8:49 am

PROJECTED DATA CHART REVISED (Lithotripsy Only)

Give information for the two (2) years following completion of this proposal. The fiscal year begins in _____.

		Year 1	Year 2
A.	Utilization/Occupancy Data (Specify unit of measure).	165	180
B.	Revenue from Services to Patients		
	1. Inpatient Services		$ -
	2. Outpatient Services	$ 1,540,704.00	$ 1,680,768.00
	3. Emergency Services	$ -	$ -
	4. Other Operating Revenue (Specify) _____		$ -
	Gross Operating Revenue	**$ 1,540,704.00**	**$ 1,680,768.00**
C.	Deductions from Operating Revenue		
	1. Contractual Adjustments	$ 941,051.84	$ 1,026,602.01
	2. Provisions for Charity Care	$ 48,722.76	$ 53,152.10
	3. Provisions for Bad Debt	$ 37,449.40	$ 40,853.89
	Total Deductions	**$ 1,027,224.00**	**$ 1,120,608.00**
NET OPERATING REVENUE		$ 513,480.00	$ 560,160.00
			$ -
D.	Operating Expenses		
	1. Salaries and Wages	$ 18,067.50	$ 19,710.00
	2. Physicians' Salaries and Wages		
	3. Supplies	$ 5,134.80	$ 5,601.60
	4. Taxes		
	5. Depreciation		
	6. Rent		
	7. Interest, other than Capital		
	8. Management Fees:		
	a. Fees to Affiliates		
	b. Fees to Non-Affiliates		
	9. Other Expenses	$ 396,000.00	$ 432,000.00
	Specify: _____		
	Total Operating Expenses	$ 419,202.30	$ 457,311.60
E.	Other Revenue (Expenses)--Net		
	Specify: _____		
NET OPERATING INCOME (LOSS)		$ 94,277.70	$ 102,848.40
F.	Capital Expenditures		
	1. Retirement of Principal		
	2. Interest		
	Total Capital Expenditures	$ -	$ -
NET OPERATING INCOME (LOSS)		$ 94,277.70	$ 102,848.40
LESS CAPITAL EXPENDITURES		$ -	$ -
NOI LESS CAPITAL EXPENDITURES		$ 94,277.70	$ 102,848.40

SUPPLEMENTAL #2
August 31, 2015
8:49 am

Projected Data Chart (Lithotripsy Only)

Other Expenses:	Year 1	Year 2
Mobile Lithotripsy Lease Payments:	$396,000	$432,000

SUPPLEMENTAL #2
August 31, 2015
8:49 am

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY: TENNOVA HEALTHCARE-LAFOLLETTE MEDICAL CENTER

I, Jerry W. Taylor, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Title: Attorney

Sworn to and subscribed before me, a Notary Public, this the 31st day of August 2015, witness my hand at office in the County of Davidson, State of Tennessee.

NOTARY PUBLIC

NANCY JOHNSON
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY, TENN.
My Commission Expires MAR. 7, 2017

My commission expires _____.